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(54) **Title**: ANTIMICROBIAL ELASTOMERIC PRODUCTS

(57) **Abstract**: This invention relates to elastomeric products having an antimicrobial coating. The antimicrobial coating is comprised of iodinated resin particles incorporated in a polymer. The coatings are prepared by forming a coating mixture of polymer and iodinated resin particles in water. The coating is then applied to the elastomeric material through a dipping or spraying procedure. A thixotrope may be added to increase the uniformity of the polymer coating over the surface of the elastomeric product. The antimicrobial coatings may be applied to a variety of different elastomeric products including gloves and catheters and are capable providing a high level of protection against microbes and other contaminants.

Antimicrobial Elastomeric Products

PRIORITY CLAIM

[0001] This application claims the benefit of U.S. Provisional Application No. 61/336,099, filed on January 15, 2010, which is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

[0002] Elastomeric products, for example, disposable gloves, are used in many healthcare related applications. These gloves are used to protect the person who is wearing them from harmful microorganisms or contaminated biological fluids. The disposable gloves are usually generated from elastomeric materials such as natural rubber latex, nitrile latex, neoprene latex and polyisoprene dispersions. Such elastomeric materials are often difficult to don owing to the high coefficient of friction associated with elastomeric articles, particularly gloves. As a result, efforts have been made to facilitate the user donning and doffing the gloves. Traditionally, a powder such as starch is placed on the inside of a glove to serve as a lubricant. However, such lubricants are often problematic, particularly in surgery, being that powders come loose during the surgical procedures. As a result, significant effort has been devoted to the production of powder-free gloves. The majority of powder-free gloves being used today have a polymer coating or are chlorinated on the inner surface of the glove. The polymer coatings must be durable and must adhere to the underlying elastomeric material.

[0003] A lubricant may also be applied to the outer (exterior) surface of the glove. One reason to add a lubricant is to prevent gloves from sticking together when packaged. The outer surface of the glove may be designed to be less slippery than the inner surface. With surgical gloves, for example, it is important that the surgeon be able to firmly grip necessary equipment and tools to perform a particular procedure. Hence, the gloves should retain a tactile feel. The lubricant used on the outer glove may be a powder or a halogenated product such as bromine or chlorine. Alternatively, the lubricant may be a polymer, such as a crosslinked polymer.

[0004] One problem with commercially available disposable gloves is that they often, during use, come in contact with exposed surfaces, potentially contaminating the surface. This is particularly an issue during surgeries, medical examinations and dental procedures where the gloves used by a doctor or dentist are exposed to dangerous microbes. Besides contaminating surfaces, there is the potential for cross-contamination of other patients and contamination of the doctor or dentist wearing the gloves.

[0005] In addition to elastomeric gloves, other elastomeric materials benefit from antimicrobial coatings, including prophylactics (*e.g.* condoms) and catheters. The widespread use of respiratory catheters, venous and or arterial catheters and urological catheters has resulted in dangerous infections owing to the adherence and colonization of pathogens on the catheter surface. Moreover, colonized catheters may produce a reservoir of resistant microorganisms. Catheter-associated urinary tract infections are now the most common type of hospital acquired infection. Catheter-related bloodstream and respiratory infections are also very common and often result in morbidity. Antimicrobial catheters currently on the market have been shown to offer some degree of protection against dangerous microbes. These catheters use various active agents such as ionic silver, chlorhexidine and antibiotics. However, commercially available antimicrobial catheters have considerable drawbacks including a narrow range of activity and the potential to cause undesirable side effects. Furthermore, development of bacterial resistance against these active agents is quite common, rendering them ineffective.

[0006] Thus, there exists a need to develop elastomeric products such as gloves and catheters that have strong antimicrobial properties such that microbes are not spread when they touch or come in contact with surfaces and/or patients. Ideally, the gloves should be highly efficacious against a wide array of microorganisms.

SUMMARY OF THE INVENTION

[0007] In accordance with this invention the aforementioned goals have been met with new antimicrobial coatings for polymeric products. The antimicrobial coatings are polymers incorporating an iodinated resin, which provides a beneficial tool against infectious disease transmission. The inventive coatings may be used to coat a host of articles such as gloves, prophylactics (e.g. condoms), catheters and tubing dental dams to mention a few.

[0008] In one aspect, the invention is directed to an elastomeric product having a foundation comprising an elastomeric material and a coating applied over the foundation, the coating comprising iodinated resin particles incorporated in a polymer. In preferred embodiments, the polymer is selected from the group consisting of a polyacrylic, polyurethane, modified polyacrylic, hydrogel polymer, polyacrylic/polyurethane blend, and acrylonitrile-based polymer.

[0009] In certain preferred embodiments, the elastomeric product is a glove. In certain embodiments, the elastomeric product is a catheter. In alternative embodiments, the elastomeric product is a condom.

[0010] In another aspect, the invention is directed to an elastomeric product having a foundation comprising an elastomeric material and a polymeric coating containing iodinated resin particles, wherein the coating is uniformly distributed over the surface of the foundation. Preferably, the iodinated resin is uniformly distributed within the coating.

[0011] In yet another aspect, the invention provides a method for preparing a coated product with enhanced antimicrobial properties, the method comprising the steps of: providing an elastomeric foundation a form of the product, preparing a coating mixture comprising an aqueous solution containing a plurality of iodinated resin particles and a polymer, and applying the coating mixture to the foundation and allowing the coating mixture to dry. Preferred polymers include polyacrylics, polyurethanes, modified polyacrylics, hydrogel polymers, polyacrylic/polyurethane blends, and acrylonitrile-based polymers. The coating mixture may optionally contain a thixotrope.

DETAILED DESCRIPTION OF THE INVENTION

[0012] The following sections describe exemplary embodiments of the present invention. It should be apparent to those skilled in the art that the described embodiments of the present invention provided herein are illustrative only and not limiting, having been presented by way of example only.

[0013] Throughout the description, where items are described as having, including, or comprising one or more specific components, or where processes and methods are described as having, including, or comprising one or more specific steps, it is contemplated that, additionally, there are items of the present invention that consist essentially of, or consist of, the one or more recited components, and that there are processes and methods according to the present invention that consist essentially of, or consist of, the one or more recited processing steps.

[0014] It should be understood that the order of steps or order for performing certain actions is immaterial, as long as the invention remains operable. Moreover, two or more steps or actions may be conducted simultaneously. Scale-up and/or scale-down of systems, processes, units, and/or methods disclosed herein may be performed by those of skill in the relevant art.

Processes described herein are configured for batch operation, continuous operation, or semi-continuous operation.

[0015] The present invention relates generally to elastomeric articles having a polymer coating, wherein said coating contains a sufficient amount of iodinated resin powder to impart antimicrobial properties to the treated articles. The elastomeric products are preferably gloves, catheters, prophylactics or elastomeric films. The purpose of the iodinated resin is to provide an enhanced barrier of protection to the elastomeric while reducing the risk of exposure to infectious pathogens in both healthcare and non-healthcare settings. The present invention is further directed to the production of such an antimicrobial elastomeric articles.

[0016] Iodine/resin demand disinfectants are known in the art. For example, U.S. Patent No. 5,639,452 ("the '452 patent"), to Messier, the entire contents which are hereby incorporated by reference, describes a process for preparing an iodine demand disinfectant resin from an anion exchange resin. The demand disinfectant iodinated resins described in the '452 patent may be ground into a powder. One preferred demand disinfectant iodinated resin is Triosyn® brand iodinated resin powders made by Triosyn Research Inc., a division of Triosyn Corporation of Vermont, USA. The particle sizes of the powders range from about 1 micron to about 150 microns. Preferably, the particle sizes should be in the range from about 4 microns to about 10 microns.

[0017] Triosyn® iodinated resin powders used in accordance with the present invention are referred to as Triosyn® T-50 iodinated resin powder, Triosyn® T-45 iodinated resin powder, Triosyn® T-40 iodinated resin powder or Triosyn® T-35 iodinated resin powder. The base polymer used to manufacture such iodinated resins is Amberlite® 402 OH (Rohm & Haas). These resins contain quaternary ammonium exchange groups with are bonded to styrenedivinyl benzene polymer chains. Other base polymers could be used. The numbers refer to the approximate weight percentage of iodine relative to the resin. Powders with other weight percentages of iodine may also be used in accordance with the present invention. Different percentages of iodine in the iodinated resin powders will confer different properties to the powder, in particular, different levels of biocidal activity. The particular resin used is based on the desired application. It is important to note that iodinated resin from other sources can also be used.

[0018] In accordance with the present invention, the Triosyn® iodinated resin powders are incorporated into a polymer and the resultant polymer/Triosyn® iodinated resin powder is used to coat a surface of an elastomeric article. Besides rendering biocidal properties to the surface of the elastomeric article, the polymeric coating serves as a lubricant to reduce the tackiness of the rubber surface. A variety of polymers may be used including but not limited to polyacrylics, polyurethanes, modified polyacrylics, hydrogel polymers, polyacrylic/polyurethane blends, and acrylonitrile-based polymers. Cross-linkable polymers such as cross-linkable acrlylics may be used to coat the rubber surface.

[0019] One embodiment of the present invention involves the production of elastomeric gloves coated with a polymer containing a halogenated resin powder. The antimicrobial gloves may be used as surgical gloves, physician or dental examining gloves, work gloves or laboratory gloves. Properties of the gloves, including thickness of the polymer coating, may be varied based on the desired application of the glove.

[0020] The underlying glove to be coated (*i.e.* glove foundation) is preferably comprised of an elastomeric material. The outside surface of the glove foundation must have the ability to be coated with a polymer containing Triosyn® iodinated resin powder while retaining its desirable properties including elasticity, stretchability, and durability. Any suitable elastomeric materials may be used in accordance with the present invention. For example, the glove may be formed from a synthetic or a natural latex, a nitrile rubber, or a natural rubber. Additionally, the glove may be formed form a homopolymer or heteropolymer of a conjugated diene. One such polymer is polyvinyl chloride.

[0021] The inner surface of the glove foundation that comes in contact with the hand of a user may optionally contain a lubricant which facilitates donning and doffing the glove. The inner and / or outer surface may be coated with a powder, a halogen or a polymeric material. Alternatively, the inner surface of the glove foundation may be coated with the same lubricant as used to coat the outer surface of the glove foundation, that is, a polymer containing a halogenated (Triosyn®) resin powder.

[0022] The coated antimicrobial gloves of the present invention can be manufactured by dipping an elastomeric glove, such as a latex or nitrile glove, into a coating mixture which contains an aqueous dispersion of polymer and the Triosyn® iodinated resin powder. The coating mixture is prepared by mixing the polymer and Triosyn® iodinated resin powder in water. The thickness of the coating on the glove will partially depend on the weight percentage of the polymer in the aqueous dispersion. Larger weight percentages of polymer in the coating mixture generate thicker outer coatings on the glove. The dip-coating procedure will be discussed in greater detail below.

[0023] Any other method of coating an article may also be used in accordance with the present invention. For example, the coating may be sprayed onto the elastomeric material.

[0024] The weight percentage of polymer in the coating mixture may be varied and will generally depend upon the nature of the underlying elastomeric coating, the chemical makeup of the polymer used as the coating, the iodine content of the Triosyn® iodinated resin powder and the desired application of the glove. In general, the weight percentage of the polymer may be from about 10% w/w aqueous solution to about 90% w/w aqueous solution. More preferably, the weight percentage of the polymer may be from about 20% w/w aqueous solution to about 60% w/w aqueous solution. More preferably, the weight percentage of the polymer may be from about 25% w/w aqueous solution to about 40% w/w aqueous solution.

[0025] One example of a polymeric coating used in accordance with the present invention is an acrylonitrile-based surface lubricant referred to as Ayclaron (also known as Ayclaron-324), which is manufactured by Innovative Polymer Systems. The coating mixture is prepared by adding Ayclaron and the Triosyn® iodinated resin powder to deionised water and then mixing. A latex or nitrile glove is then coated with the Ayclaron polymer by dipping the glove into the coating mixture and subsequently drying or spraying the coating mixture on the glove (a two step spray is also acceptable where first spray is water and coating followed by a water and Triosyn® iodinated resin particle).

[0026] The polymeric coating on the glove should be able to secure the Triosyn® iodinated resin powder sufficiently. The Triosyn® iodinated resin powder should not rub off the glove. Furthermore, the coating should be able to withstand contact with various surfaces without losing the Triosyn® resin powder. At the same time, there should be enough iodinated resin in the polymer to exert a toxic effect on a large variety of different microbes. Moreover, the coating should not hinder the user from handling objects. Determining the appropriate weight percentage of polymer (*e.g.* Ayclaron) in the mixture used to make the coating is thus a factor in manufacturing an antimicrobial glove with optimal properties.

[0027] As an example, we performed several experiments to determine the optimal thickness of Ayclaron and the ratio of Triosyn® iodinated resin powder to use in coating a latex glove. Initially, the coating mixture was prepared in a 10% w/w aqueous solution. After the latex gloves were coated with the coating mixture, they were dried and subjected to various tests, as described in more detail below. We found that there was insufficient polymer on the coating of the gloves and that the Triosyn® iodinated resin powder fell off.

[0028] We then tested the effect of using higher concentrations of polymer in the coating mixture. Aqueous solutions using 60% w/w Ayclaron or 90% w/w Ayclaron and 2% w/w Triosyn® T-50 resin powder were made and the latex gloves were dipped into the coating mixture and subsequently dried. Difficulties with drying rates were encountered for both concentrations and after the usual 20 minutes at 40°C, the temperature was increased to 50°C. For the 60% w/w Ayclaron, 20 additional minutes were needed and the 90% w/w Ayclaron needed an additional 40 minutes at the elevated temperature to dry the gloves. For both concentrations, it was found that the Triosyn® iodinated resin powder did not fall off the gloves. However, the coating on the latex gloves was brittle and upon stretching of the glove, cracking occurred. Hence, the physical properties of the gloves were not acceptable.

[0029] We found that for the elastomeric gloves of the present invention, coatings made from aqueous solutions of from about 20% w/w Ayclaron polymer to about 40% w/w Ayclaron polymer gave the desired properties of the antimicrobial gloves. At these concentrations, the amount of Triosyn® iodinated resin powder added to the aqueous coating mixture will vary as a function of the Triosyn® iodinated resin powder used. For instance, with gloves manufactured using the Triosyn® T-50 iodinated resin powder, 1%-2% w/w of the powder was added. The resultant latex gloves with the Ayclaron/Triosyn® iodinated resin powder coating did not shed the resin powder. With Triosyn® T-45 iodinated resin powder, about 4% w/w of the resin powder was added and shedding was not observed. The gloves had good general uniformity and physical resistance.

[0030] Having developed gloves with the appropriate physical characteristics, we then assessed the antibacterial effect of the gloves. The experiments used to test biocidal activity are described in greater detail in the examples below. The antimicrobial efficiency of the gloves was determined using *Staphylococcus aureus* as the challenge organism. The gloves were allowed to contact the organism for up to 30 minutes and measurements were taken at various time points. Gloves coated with 25% Ayclaron and Triosyn® T-45 iodinated resin powder and gloves coated with 25% Ayclaron and 2% Triosyn® T-50 iodinated resin powder showed outstanding antimicrobial efficacy.

[0031] Latex gloves coated with a 35% w/w Ayclaron mixture were also prepared. As expected, the higher concentration of polymer was able to incorporate a larger amount of Triosyn® iodinated resin powder without a significant degree of shedding the resin powder. Hence, aqueous mixtures of 35% Ayclaron were prepared which were able to incorporate 4% Triosyn® T-50 resin powder or 6% Triosyn® T-45 iodinated resin powder. It was anticipated that the gloves with the 35% w/w Ayclaron coating would be even more efficacious than the gloves with the 25% w/w Ayclaron coating owing to the fact that the gloves with a higher weight percentage of polymer can hold more Triosyn® iodinated resin powder. However, it was found that the latex gloves coated with 35% Ayclaron and Triosyn® iodinated resin powder were less efficacious then the gloves coated with 25% Ayclaron and 4% Triosyn® iodinated resin powder. We suspect that when the coating on the latex glove exceeds a certain thickness, the Triosyn®

iodinated resin powder becomes embedded in the polymer, which hinders its antimicrobial efficacy.

[0032] Antimicrobial nitrile gloves were also prepared by the same procedure used to coat the latex gloves. The nitrile gloves were also evaluated for suitable coating mixtures. Aqueous mixtures of 25% w/w Ayclaron and 2%-4% Triosyn® T-50 iodinated resin powder were used to coat the nitrile gloves. Additionally, aqueous mixtures of 35% w/w Ayclaron and Triosyn® T-50 iodinated resin powder (2-4% w/w) were used to coat the nitrile gloves. Furthermore, aqueous mixtures of 35% w/w Ayclaron and Triosyn® T-45 iodinated resin powder (3-6%) were used as coatings. The Triosyn® iodinated resin powder did not come off the coated nitrile gloves. Furthermore, as with the coated latex gloves, the coated nitrile gloves showed a high level of antimicrobial efficacy in a time-dependent manner.

[0033] As discussed above, a variety of different polymers can be used to coat the materials of the present invention. In addition to the acrylonitrile-based polymers discussed in the preceding paragraphs, preferred polymers include polyurethanes, modified polyacrylics, hydrogel polymers, and polyacrylic/polyurethane blends. The general procedure for coating the elastomeric materials with these polymers is the same as described above for coating with Ayclaron. It will be appreciated that the optimal weight percentage of the polymer and the Triosyn powder will vary with the polymer being used.

[0034] One preferred method of producing the coated elastomeric articles of the present invention is through a dip-coating procedure. In a standard dip-coating process, the elastomeric articles is placed on a form. The form containing the elastomeric article is placed into the coating mixture until the proper depth is achieved. At this point, the elastomeric article is extracted from the aqueous dispersion (coating mixture) while rotating the article around its vertical axis. The elastomeric article continues rotating while drying. To ensure uniformity of the coating over the outer surface of the glove foundation, the rotation pattern is optimized to distribute the polymeric/Triosyn® iodinated resin powder over the glove surface with a degree of uniformity. Such a rotation pattern involves varying the axial rotation rate in an attempt to even flow based on judgement and observation of flow pattern over the surface of the elastomeric article.

[0035] Alternatively, we have found that the incorporation of a thixotrope or associative thickener into the coating mixture facilitates even distribution of the coating over the glove foundation. A thixotrope is defined as additive that modifies the rheology of a fluid so that the fluid is shear thinning. The addition of a thixatrope to an aqueous mixture of a polymer containing Triosyn® iodinated resin powder will give a thin, flowable substance when it is under shear and a gel when it is free of shear. When under shear, the weak gel structures of the thixotrope are broken down. When the sheer is removed, the gel structures are reformed. As a result, compositions become less viscous when subjected to low shear forces and more viscous when they are not being agitated. When compositions containing thixotropes are applied as coatings, they will flow out even when dipped, brushed or sprayed but then return to a gel state when the shear is removed.

[0036] The thixotrope can be added to a coating mixture containing a polymer and an antimicrobial particulate (e.g. Triosyn® iodinated resin powder) to ensure uniform distribution of the antimicrobial particulate in a dip tank or day tank. Moreover, it has been found that when such a composition is used to coat an elastomeric article, the polymer and the antimicrobial particulate are uniformly distributed over the surface of the article. Additionally, applying such a coating to the elastomeric article facilitates the process involved in evenly distributing the particulate on the article.

[0037] To minimize the effects of lack of uniform distribution, a thixotrope or other viscosity modifying agent is incorporated into the aqueous mixture of polymer/Triosyn® iodinated resin powder to provide a higher viscosity, therefore immobilizing the Triosyn® iodinated resin powder while in the dip tank. The polymer and Triosyn® iodinated resin powder are then applied to the dipped article. Low sheer thixotropes are utilized in quantities of 0.5 – 10.0% w/w percent of the entire mix, with 1.5 – 3.0% w/w being preferred. This concentration range facilitates a viscosity (depending upon the polymer family and concentration) that will prevent the Triosyn® particulates from settling. Yet when the article to be coated is immersed into and extracted from the mixture, the low shear of the object entering and exiting the dispersion will provide a drop in viscosity at the dispersion/article interface sufficient to apply a limited amount of dispersion to be lifted from the mixture.

[0038] As the article exits through the surface of the mixture, the viscosity of the mixture that has been deposited on the article at the meniscus between the mixture surface and the article surface interface will increase sufficiently to eliminate or minimize the gravitational flow of the mixture that has been deposited on the article surface. This facilitates a more even distribution of Triosyn® iodinated resin powder and polymer over the surface and stabilizes the yet fluid coating to a sufficient degree to stop the migration of Triosyn® iodinated resin powder in the yet fluid coating.

[0039] Various types of thixotropes may be used in accordance with the present invention. Both polymeric and nonpolymeric thixotropes may be employed. Suitable thixotropes include polyurethanes, polyacric acids, crosslinked polyacrylic acids (e.g. Carbapol polymers), polyvinylpyrrolidone, xanthan gum, locust bean gum, urea, fumed silica, precipitated silica, organomodified clays, basic calcium disulfate gels, cellulose acetate and precipitated calcium carbonate. Particularly preferred thixotropes include polyvinylpyrrolidone, Acrysol ASE-60 (An acrylic emulsion copolymer) and Rheolate 288 (a polyether urea polyurethane).

[0040] Other viscosity modifying agents besides thixotropes may be used in accordance with the present invention. For example, associate thickeners may be used in place of or in combination with a thixotrope. Associate thickeners have low molecular weight hydrophilic polymers with nonpolar groups spaced along the backbone. Associate thickeners have excellent flow properties. Examples of associate thickeners to be used in the present invention include but are not limited to hydrophobe modified ethoxylate urethanes, hydrophobe modified ethoxylate ureas, and hydrophobe alkali-swellable emulsions.

[0041] It is recommended that in addition to using a viscosity-modifying agent in the coating mixtures, a dispersing agent such as surfactant be added. A suitable surfactant to be used in accordance with the present invention is Mirataine H2C-HA surfactant (an alkylamino propionate amphoteric surfactant). Other surfactants include but are not limited to benzalkonium chlorides, hexadecyltrimethylammonium chloride, dodecylpyridinium chloride, the corresponding bromides, a hydroxyethylheptadecylimidazolium halide, coconut alkyldimethylammonium betaine and 1-hexadecylammonium chloride monohydrate.

[0042] As discussed above, the thickness of the coating applied to the elastomeric material will be partially dependent on the weight percentage of polymer used in the coating mixture. Additionally, the thickness of the coating may be varied by modifications in the extraction rate of the elastomeric article from the coating mixture. The amount of polymer or modified polymer coating that is picked up by the surface of an article as it is being extracted is proportional to the speed of extraction. The meniscus that is developed at the surface interfaces decreases or increases as the speed of extraction increases or decreases. This interfacial meniscus is where the pick-up of the polymeric or modified polymeric dispersion occurs.

[0043] As the speed of extraction is increased, the meniscus formed between the article and dispersion surface is increased, facilitating an increase in the amount of dispersion pick-up. Conversely, as the speed is decreased, the meniscus between the article and dispersion surface is decreased, facilitating less dispersion pick-up.

[0044] If the speed of extraction is sufficiently high, then he resultant pick-up that occurs on the article will have a propensity to run or and/or drip from the article surface. This may be undesirable in some critical applications where poor or inadequate distribution of the coating or it's modifiers (particularly particulate antimicrobials) may have a negative effect on the finished product efficacy.

[0045] The antimicrobial coatings of the present invention may be used to coat a variety of other elastomeric articles in addition to gloves. One example of the type of products that can be used in accordance with the present invention is a catheter coated with a Triosyn® iodinated resin powder/polymer. Catheters are an indispensable tool in the medical field that help with drainage of numerous fluids (urine, blood, abscess, etc.). Catheters are lubricated on their outer surface to facilitate insertion through a luminal orifice on of a human body. Although there are numerous catheters with coatings that combat infections currently on the market, Triosyn® coated catheters have an advantage due to the wide scope of antimicrobial activity thus imparted.

[0046] The procedure for coating the catheters is generally the same as the procedure used to coat the nitrile and latex gloves. For example, latex urological catheters were coated with a mixture of Triosyn® iodinated resin powder/ Ayclaron polymer.

[0047] Another aspect of the present invention involves coating prophylactics with a Triosyn® iodinated resin powder. For example, the coatings of the present invention may be used to coat condoms. The procedure for coating the condoms is generally the same as the procedure used to coat the nitrile and latex gloves.

[0048] In the example of the spray method above described , the coating can also be applied to non-woven , woven , film porous or non porous.

[0049] The present invention is illustrated by the following examples. The examples should not be interpreted as limiting he scope of the present invention.

Method of Coating Gloves

Preparation of 25% Ayclaron Coating Mixture Containing Triosyn® Iodinated Resin Powder

[0050] A variety of different concentrations of polymers containing Triosyn® iodinated resin powder were prepared. As an example, a coating mixture of 25% (by weight) Ayclaron Polymer was prepared as follows:

i. Calculate the necessary weights of water and Ayclaron polymer in order to make a 25% w/w coating mixture. For an 800 g mixture of 25% w/w Ayclaron/ water: 200 g Ayclaron and 600 g high purity water (reverse osmosis, deionised) are required.

ii. Place a 1L beaker on an analytical balance. Tare the beaker. Carefully add Ayclaron polymer pouring into the beaker until the desired weight is achieved. Use a Pasteur pipette for the last few grams.

iii. Carefully add high purity water up to the required mass. Use a Pasteur pipette for the last few grams.

iv. Place the beaker containing Ayclaron/water mixture on a stir plate. Add an elongated stir bar to the beaker. Set the stir speed to setting 7. (Note: may need to manually stir with a glass rod in order to dislodge any remaining polymer which may be stuck to walls.) Cover and mix the solution for 15 minutes.

v. Calculate the amount of Triosyn® iodinated resin powder and 25% Ayclaron solution which will be required for the desired concentration. For example, for a 2% w/w Triosyn® powder in an Ayclaron 25% Solution (800 g solution), 16 g of Triosyn® T-45 resin powder and 784 g of 25% Ayclaron solution for a total of 800 g.

vi. Place a 1L beaker on an analytical balance. Tare the beaker. Carefully add the 25% Ayclaron polymer aqueous solution pouring into the beaker until the desired weight is achieved. Use a Pasteur pipette for the last few grams.

vii. Carefully add Triosyn® iodinated resin powder to the 25% polymeric coating solution to form an aqueous dispersion containing Ayclaron polymer and Triosyn® iodinated resin powder.

viii. Place a beaker with the newly made solution onto a stir plate. Stir overnight to obtain a homogeneous dispersion.

Application of Iodinated Resin /Ayclaron Mixture to Gloves (Latex or Nitrile)

[0051] After the coating mixture is prepared, the gloves were coated by using a dipping process. The following steps are involved in coating disposable latex or nitrile gloves:

i. Preheat the oven to 40°C. Line the bottom of oven with absorbent paper towels.

ii. Prepare the gloves to be dipped in the coating.

iii. Hold glove at wrist/opening with one hand.

iv. Inject air into the glove using the air gun to fill the glove up with a volume similar to a hand.

v. Hold and seal by twisting a knot in the glove (about 2-3 turns is sufficient).

vi. Place the beaker containing the Triosyn® iodinated resin powder/Ayclaron coating mixture onto a stir plate. Carefully dip the glove into the beaker. Notably, the complete glove is not immersed. Only about 80% of the glove is immersed due to the sealing at the top of the glove.

vii. Soak the glove for approximately 5-10 seconds. Carefully remove the glove from the mixture. Use paper towels to collect any solution which will drip from the glove's fingertips.

viii. Dry gloves in the oven for a duration of 20 minutes.

[0052] Control samples with no Triosyn® iodinated resin are also prepared in the same manner. However, they are to be dipped in 25% w/w polymer (*e.g.* Ayclaron) only (no Triosyn® iodinated resin powder).

Preparation of Coating Mixture With Thixotrope

[0053] The formulation ("coating mixture") for dipping gloves is based on a total solution weight of 2000 grams. The ingredients the *polymer concentrate*, Mirataine H2C-HA surfactant, distilled H_2O, 1 N KOH, Triosyn® iodinated resin powder and a compatible thixotrope.

[0054] For this example, the polymer concentrate contains 35% total *polymer solids*. The polymer solids used in the present example are Witcobond 321, which is a polyurethane dispersion. If it is desired that the dip solution concentration to be 5% polymers solids, 100 grams (2000 x 0.05) will be required for the mixture. Hence, with a concentrate of 35% polymer solids, 100g/0.35 = 333.3 grams of polymer concentrate is required for the dip solution. If the Triosyn® iodinated resin powder concentration is to be 5%, 2000 x0.05 = 100 grams of Triosyn® iodinated resin powder is required for the dip solution. Hence, the total non-aqueous materials are 433.3 grams. Accordingly, 2000-433.3 = 1566.7 grams distilled water will be added.

[0055] The general procedure for making the coating mixture involves making two pre-mix solutions and then combining. Half of the required water (783.4 grams) is used to make the Triosyn® iodinated resin powder pre-mix solution (a dispersion of Triosyn® iodinated resin powder in water) and half of the water is used to make the polymer concentrate pre-mix solution.

[0056] To make the Triosyn® iodinated resin powder pre mix solution, 783.4 grams of water were placed in an Erlenmeyer flask (100 mL) and 40 drops of Mirataine H2C-HA surfactant was added. The pH of the water/surfactant solution was adjusted to the pH of the polymer concentrate by adding KOH. Next, the Triosyn® iodinated resin powder (100 grams) was added and the solution was stirred for two hours to ensure proper wetting and dispersion of the Triosyn® particulates. The Triosyn® iodinated resin powder pre-mix was stirred was stirred at 400 rpm the entire time to prevent agglomeration.

[0057] To make the polymer concentrate solution, the thixotrope Rheolate 288 (1.5% w/w of the total mix) was added to a flask containing 783.4 grams of water. The solution was stirred at 400 rpm until the thixotrope was properly dispersed in the water. The pH of the solution was adjusted to the pH of the polymer concentrate. While stirring, the polymer concentrate was added to the flask.

[0058] Next, the Triosyn® iodinated resin powder pre-mix solution and the polymer concentrate solution were combined to form an aqueous dispersion. It may be necessary to increase the stirring rate when combining the two solutions. The stirring was continued for an additional 15 minutes and then the stirring rate was reduced while maintaining movement of the combined pre-mixes.

Dip Coating a Glove with Coating Mixture Containing Thixotrope

[0059] Place glove on the form stretching it slightly to remove any wrinkles. Secure the cuff of the glove with a strong elastic band while it is stretched. Do not over stretch, just enough elongation to remove wrinkles. Using a soft brush, thoroughly scrub the glove with dish detergent and warm water being sure to scrub between the fingers. When the glove is thoroughly scrubbed, rinse in cold tap water to remove all detergent. Dry glove by patting with paper towel and then place in air current (preferably an outflow hood) to complete drying.

[0060] When the glove is dry, dip it into the polymer/Triosyn® iodinated resin powder dispersion ("coating mixture"). Prior to dipping the glove/form into the mixture, decrease the stir rpm to 60 and allow the mixture to decrease its velocity before dipping. Place the glove into the mixture until the proper dip depth is achieved. At this point begin the extraction of glove from the mixture while rotating the glove slowly around it's vertical axis. When the finger tips have exited the mixture, angle the finger tips upward at approximately 35 - 45 degree angle while rotating around axis at approximately 10 - 15 rpm (estimated). When the mixture is observed to be flowing toward the palm, angle the finger tips downward at approximately 35 - 45 degrees while rotating the glove slowly around it's axis.

[0061] Continue this axial rotation and angling of finger tips while observing the mixture flow over the glove surface. This is done in an effort to distribute the polymer/Triosyn® iodinated resin powder over the glove surface with a degree of uniformity. Axial rotation rpm may be increased or decreased in attempt to even flow based on judgment and observation of flow pattern over surface. Continue until the solution does not appear to flow. At this time, move the form to a horizontal position but maintain the axial rotation (slower) until there is no moisture apparent on the surface. Stand the glove in the outflow hood to continue drying. Place the glove and form in a dispatch oven (70 - 80°C) for 15 minutes. Remove the glove and allow the glove and form to cool to RT. Remove glove from form.

Spray Coating a Glove with Coating Mixture Containing Thixotrope

[0062] Mixing of the Triosyn® iodinated resin powder and polymeric pre-mixes should be conducted as per the procedure detailed in Dip Solution and Dipping Procedure document.

[0063] The pre-mix and dispersion of Triosyn® iodinated resin powder is of primary importance for spray coating. If the agglomerations that are experienced with the dry Triosyn® iodinated resin powder are mixed into water without the addition of surfactant, the agglomerations may not disperse (separate to the lowest possible particulate size) properly. If the particulates are not reduced to their smallest available particles (no agglomerations) the nozzle of the spray apparatus may plug.

[0064] After the pre-mixes are combined they may be added to conventional spray pressure pot for delivery to the spray gun/nozzle. If the mixture does not contain a thixotrope the pressure pot must have an auxiliary mixer incorporated in order to maintain a homogeneous dispersion within the mixture prior to transport to the spray gun. If the mixture sits stagnant, the Triosyn® particles will precipitate and therefore be transported to the gun in a disproportionate quantity to the predetermined polymer/Triosyn® iodinated resin ratio.

[0065] A thixotrope can be incorporated in the range of 2.0 – 2.5% w/w of the total mix weight to prevent Triosyn® iodinated resin powder from precipitating. The spray nozzle orifice does not require enlargement as the pressure delivering the mixture to the nozzle is sufficient to create flow through the nozzle.

EXPERIMENTAL RESULTS

A. Swab Tests

[0066] A very simple test was designed to determine how well the coating has bonded to the glove with the use of an analytical balance. A cotton swab tip is used to rub a 12.56 cm^2 section of the glove with a pressure of 0.2kg/cm^2. The balance is used to determine the exact amount of pressure to apply to the swatch. A pass is obtained if no Triosyn® iodinated resin powder transfer occurs onto the cotton. A fail results when Triosyn® iodinated resin powder is removed from the glove.

[0067] The results for several of the swab tests are presented below in Tables 1 and 2. Table 1 presents results with latex gloves while Table 2 presents results with nitrile gloves. Note that the concentrations tested below were the final results obtained that met expectations. Numerous trials with various other concentrations of the Triosyn® iodinated resin powders as well as Ayclaron prior to trials with the 25% or 35% w/w Ayclaron solution were performed with inadequate results. The rejected results were based on numerous criteria such as failures in the swab tests, or non-uniform coatings.

Table 1:

Swab Test Results and Microscopic Inspection Observations of Triosyn® Iodinated Resin Powder in a 25% and a 35% Ayclaron Coating on Disposable Latex Gloves

Triosyn/Ayclaron Concentrations Coated on the Latex glove	Swab Test Pass/Fail
2% T-45 Triosyn/ **25%** Ayclaron Mixture	Pass
4% T-45 Triosyn/ **25%** Ayclaron Mixture	Pass
6% T-45 Triosyn/ **35%** Ayclaron Mixture	Pass
1% T-50 Triosyn/ **25%** Ayclaron Mixture	Pass
2% T-50 Triosyn/ **25%** Ayclaron Mixture	Pass

Triosyn/Ayclaron Concentrations Coated on the Latex glove	Swab Test Pass/Fail
4% T-50 Triosyn/ **35%** Ayclaron Mixture	Pass

Table 2:

Swab Test Results and Microscopic Inspection Observations of Triosyn® Iodinated Resin Powder in a 35% Ayclaron Coating on Disposable Nitrile Gloves

Triosyn/Ayclaron Concentrations Coated on the Nitrile glove	Swab Test Pass/Fail
3% T-45 Triosyn/ **35%** Ayclaron Mixture	Pass
6% T-45 Triosyn/ **35%** Ayclaron Mixture	Pass
2% T-50 Triosyn/ **35%** Ayclaron Mixture	Pass
4% T-50 Triosyn/ **35%** Ayclaron Mixture	Pass

B. <u>Microbiological Testing</u>

[0068] The microbiological assays were performed using a Colony Forming Unit (CFU) kit. The technique measures the viability of microorganisms on an Agar plate. The antimicrobial efficacy was also evaluated using *Staphylococcus aureus* as a challenge micro-organism. The method used involved deposition by gravity of a nebuliser spray containing the bacteria followed by liquid recovery “environment” protocol. The nebulized solution consists of the bacteria in a solution of Phosphate Buffer Saline (PBS) and Fetal Bovine Serum (FBS). The evaluation was performed on 1” x 1” swatches of latex or nitrile gloves containing the Triosyn® iodinated resin powder/Ayclaron as well as on a control, the glove coated with only the 25% Ayclaron polymer. Different contact times of 5, 10 and 30 minutes were evaluated.

[0069] The following general procedure was used for microbiological testing.

i. Inoculate the samples (latex or nitrile) laid on the bottom of aerosolization chamber with approximately 1x10^6 *Staphylococcus aureus* using the nebuliser spray (PBS + 5% FBS) for approximately 10 minutes to create an aerosol saturating the chamber. Allow the bacteria to settle (or deposit) on the samples for approximately 15 minutes.

ii. Place samples in an incubator at 37°C and at indicated time points, place sample in 50mL conical tube containing 10mL of PBS with 0.1% Thiosulfate and vortex for 30 seconds. The bacteria will be extracted into the PBS/thiosulfate solution.

iii. Perform serial dilutions on the PBS/thiosulfate extract from the previous step and plate. Determine the colony count on the plate.

[0070] The results for the microbiological tests with the Triosyn® iodinated resin powder/Ayclaron coated latex gloves are presented below in Table 3 with contact times of 5, 10 and 30 minutes. The results show that several of the coated gloves have a high degree of efficacy judging by the % reduction of bacteria. On latex gloves, the best final concentration based on the results was found to be the latex glove coated with 25% Ayclaron and 4% Triosyn® T-45 iodinated resin powder (0-10μm) and 25% Ayclaron and 2% Triosyn® T-50 iodinated resin powder.

Table 3:

Microbiological Results

SAMPLE DESCRIPTION	Time	CFU	% Reduction
Latex glove coated with 25% Ayclaron	5 min	2.34E+06	0.00%
	10 min	2.64E+06	0.00%
	30 min	1.30E+06	0.00%
Latex glove coated with 35% Ayclaron	5 min	1.20E+06	25.53%
	10 min	N / A	N / A
	30 min	3.08E+06	0.00%

SAMPLE DESCRIPTION	Time	CFU	% Reduction
Latex glove coated with 25% Ayclaron + 2% Triosyn T45	5 min	2.24E+05	88.33%
	10 min	2.77E+05	84.49%
	30 min	1.33E+05	86.09%
Latex glove coated with 25% Ayclaron + 4% Triosyn T45	5 min	7.05E+04	96.33%
	10 min	8.13E+04	95.44%
	30 min	7.50E+04	92.15%
Latex glove coated with 35% Ayclaron + 6% Triosyn T45	5 min	5.65E+05	59.69%
	10 min	7.52E+05	0.00%
	30 min	1.78E+05	33.13%
Latex glove coated with 25% Ayclaron + 1% Triosyn T50	5 min	4.65E+05	75.80%
	10 min	2.28E+05	87.20%
	30 min	2.40E+05	74.87%
Latex glove coated with 25% Ayclaron + 2% Triosyn T50	5 min	1.52E+05	92.07%
	10 min	2.90E+05	83.74%
	30 min	9.00E+04	90.58%
Latex glove coated with 35% Ayclaron + 4% Triosyn T50	5 min	3.21E+05	77.13%
	10 min	3.27E+05	21.26%
	30 min	1.96E+05	45.17%

EQUIVALENTS

[0071] While the invention has been particularly shown and described with reference to specific preferred embodiments, it should be understood by those skilled in the art that various changes in form and detail may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

CLAIMS

1. An elastomeric product with enhanced antimicrobial properties, the product comprising:

a foundation comprising an elastomeric material; and

a coating applied over said foundation, said coating comprising iodinated resin particles incorporated in a polymer, said polymer selected from the group consisting of a polyacrylic, polyurethane, modified polyacrylic, hydrogel polymer, polyacrylic/polyurethane blend, and acrylonitrile-based polymer.

2. The elastomeric product of claim 1, wherein the elastomeric material is selected from the group consisting of latex, nitrile and polyurethane.

3. The elastomeric product of claim 1, wherein said polymer is an acrylonitrile-based polymer.

4. The product according to claims 1-3, wherein the product is a glove.

5. The product according to claims 1-3, wherein the product is a catheter.

6. The product according to claims 1-3, wherein the product is a condom.

7. The elastomeric product according to any one of the proceeding claims, wherein the iodinated resin particles are evenly dispersed in the polymer.

8. The elastomeric product according to any one of the proceeding claims, wherein the polymer is evenly dispersed over the elastomeric material comprising the foundation.

9. A method for preparing a coated product with enhanced antimicrobial properties, the method comprising the steps of:

(a) providing a foundation on a form of the product, the foundation comprising an elastomeric material;

(b) optionally, applying a solvent to the foundation which would remove an existing coating of the foundation and/or prepare the surface for secondary treatment

(c) preparing a coating mixture comprising an aqueous solution containing a plurality of iodinated resin particles and a polymer selected from the group consisting of a polyacrylic, polyurethane, modified polyacrylic, hydrogel polymer, polyacrylic/polyurethane blend, and acrylonitrile-based polymer; and

(d) applying the coating mixture to the foundation and allowing the coating mixture to dry.

10. The method of claim 9, wherein said coating mixture further comprises a thixotrope.

11. The method of claims 9 or 10, wherein the coating mixture is applied using a dipping procedure

12. The method of claims 9 or 10, wherein the coating mixture is applied using a dipping procedure,

13. The method of claims 9-12, said method producing a coated product wherein the polymer is evenly dispersed over the foundation.

14. The method of claims 9-13, wherein the weight percentage of polymer in the coating mixture is from about 20% w/w to about 40% w/w.

15. The method of claim 14, wherein the weight percentage of polymer in the coating mixture is about 25% w/w.

16. The method of claim 14, wherein the weight percentage of polymer in the coating mixture is about 35% w/w

17. The method of claims 9-16, wherein the weight percentage of iodinated resin in the coating mixture is from about 1% w/w to about 6% w/w.

18. The method of claim 17, wherein the weight percentage of iodinated resin in the coating mixture is from about 2% w/w to about 4% w/w.

19. The method of claim 10, wherein the weight percentage of thixotrope in the coating mixture is between 1% w/w and 3% w/w.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/021337

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A01N 59/12 (2011.01)
USPC - 428/36.8
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) -A41D 19/00; A61F 6/04; A61M 27/00; A01N 29/00, 59/12; A01P 1/00; B23B 25/00, 25/12, 25/20, 27/00, 27/18 (2011.01)
USPC - 2/167; 424/78.1, 78.17, 669; 427/2.3, 299, 322; 428/36.8, 411.1, 422, 423.1, 492-493, 522; 525/25

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,592,861 B2 (MESSIER) 15 July 2003 (15.07.2003) entire document	1-3, 9-12, 19
Y	US 6,730,380 B2 (LITTLETON et al) 04 May 2004 (04.05.2004) entire document	1-3, 9-12, 19
Y	US 6,514,413 B2 (PIMENOV et al) 04 February 2003 (04.02.2003) entire document	3
Y	US 2006/0141186 A1 (JANSSEN et al) 29 June 2006 (29.06.2006) entire document	10, 19

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
25 February 2011	09 MAR 2011

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/021337

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

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

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

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

3. ☒ Claims Nos.: 4-8, 13-18
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.