Description

This invention relates to microbial decontamination, in particular to a method of microbial decontamination and to apparatus and other means for use therein.

The present invention relates to anti-microbial agents. It finds particular application in conjunction with automated sterilizing or disinfecting of medical instruments and will be described with particular reference thereto. However, it is to be appreciated that the present invention will find utility in sterilizing and disinfecting a wide range of objects, either automatically or manually. Heretofore, most medical instruments have been sterilized in a steam autoclave. In hospitals and large facilities, medical instruments and equipment were transported to a central sterilizing facility where they were sterilized under the supervision of sterilizing room technicians. In a steam autoclave, the equipment was subject to superheated steam at high pressures, depressurized, and cooled. One of the drawbacks of the steam autoclave is that many medical instruments cannot withstand the high temperatures and pressures. Another drawback resides in the one to two hour cycle time.

Instruments and equipment which could not withstand the pressure or temperature of the autoclave were commonly sterilized with ethylene oxide gas. The equipment was sealed in a sterilizing chamber which was pressurized with the ethylene oxide gas. After an appropriate sterilizing cycle, the equipment was degassed for twelve to sixteen hours in a vacuum or about 72 hours in ambient atmospheric conditions to remove the highly toxic ethylene oxide. One of the drawbacks to ethylene oxide sterilization resided in the long cycle times. Another drawback resided in the need for training technicians to handle the highly toxic ethylene oxide gas systems. Yet another drawback was that some medical equipment could not be sterilized with ethylene oxide gas.

Liquid sterilization systems were utilized for equipment which would not withstand the high temperatures of steam sterilization or were too expensive to use only once per day as is necessitated by the long sterilizing times of ethylene oxide sterilization. The equipment was immersed in a vat or tank that had been filled with a sterilizing solution, such as stabilized hydrogen peroxide or glutaraldehyde. Because such liquid sterilizations were normally performed manually, the skill and care of the technician were controlling factors in whether sterilization or disinfection were, in fact, attained. In many instances, the technician was required to mix the components of the anti-microbial composition. Even when mixed properly, relatively long immersion times on the order of six to ten hours were commonly required to assure sterilization. Moreover, many liquid sterilization systems were highly corrosive to metal parts, particularly brass, copper, and aluminum. With long immersion times, even brass and stainless steel could be pitted and sharp cutting edges dulled.

Peracetic acid is one of the most potent organic peroxide biocides. Peracetic acid is available in a liquid form as an equilibrium mixture with acetic acid and hydrogen peroxide. Peracetic acid is limited in its usefulness as a chemical sterilant for medical devices because it has a very low pH and is very corrosive to metals, e.g. carbon, steel, and brass, even in dilute solutions. Buffers and anticorrosive agents must be added to protect the steel and brass parts of medical instruments. However, relatively large amounts of buffering and anticorrosive agents must be employed, due not only to the low pH and acidity of the peracetic acid equilibrium mixture, but also to neutralize the effects of the biologically inert acetic acid and hydrogen peroxide. The peracetic acid and hydrogen peroxide in the equilibrium mixture tend to degrade slowly, liberating gaseous oxygen. In order to prevent gas pressure from accumulating in the containers holding the peracetic acid mixture, a venting system must be provided. The venting systems tend to vent not only oxygen, but also very corrosive and highly pungent vapors which must be neutralized by special packaging.

In the bleaching art, dry compositions have been mixed with an activator compound to release a peroxy bleaching substance. Typically, an inorganic peroxide or other hydrogen peroxide releasing agent is intermixed with an activator compound. Of the dozen or so classes of activator compounds, N,N,N',N'-tetraacetylethylene diamine (TAED) and tetraacetylglycouracil (TAGU) are most common. These activator compounds are large organic molecules with limited solubility in water. With the acid precursor compounds, having relatively low water solubilities, only small concentrations of peracetic acid can be produced. Moreover, the undissolved solids of the precursor and activator compounds become temporarily suspended in the solution and can deposit in and block small channels of immersed equipment.

GB-A- 1 566 671 discloses storable compositions for dilution with water to form anti-microbial solutions, which comprise: (A) an acyloxy-aromatic carboxylic acid and (B) a source of hydrogen peroxide.

Our EP-A-0 232 170 discloses a method of sterilizing an item which is enclosed in an interior of a module which is closed to the ambient atmosphere by causing a sterilant solution to flow into and remain in contact with the module interior until the item and the module interior are sterilized and draining the sterilant solution from the module interior and further characterized by:

(a) passing a sterile rinse fluid into the module interior to rinse the item; and,

(b) passing a bacteria-free drying gas through the module to dry the item and the module interior.

Our EP-A-0 332 310, which is an intermediate publication, discloses a microbial decontamination system comprising:

a source of water;

a container for holding an item to be microbially decontaminated;

a tubing system for providing a fluid flow path for received water from the water source to the container;

a reservoir for receiving powdered reagents including at least one of a buffer, a detergent, and anti-corrosive, and for receiving a vented ampule, the ampule comprising:

a vent passage defining a vent aperture at one end thereof;

an exterior wall surrounding the vent aperture and defining an interior volume which is less than half filled with an antimicrobial solution, the exterior wall being sealed to the vent passage;

the reservoir being connected with the tubing system such that the received water dissolves the powdered reagent; and

an antimicrobial solution discharging means for selectively discharging the antimicrobial solution from the ampule into the water.

In a first aspect the present invention provides a method of microbially decontaminating an item by immersing the item in an anti-microbial solution formed by reacting a soluble acid precurser and a soluble peracid compound in a dilutant, characterized by:

(a) measuring preselected amounts of dry reagents including the acid precurser and the peracid;

(b) packaging the measured dry acid precurser and peracid in a holder and storing the holder until items are to be microbially decontaminated;

(c) opening the holder and intermixing the dry acid precurser and the dry peracid compound with the dilutant to form the anti-microbial solution; and

(d) immersing the item in the anti-microbial solution;

the intermixing and immersing steps including:

recirculating the anti-microbial solution from a chamber in which the item is disposed through interconnecting tubing and back to the chamber, whereby the interconnecting tubing - and chamber interior are microbially decontaminated together with the item; and

the method including a rinsing step of passing a microbially decontaminated rinse liquid from a source of the rinse liquid through the interconnecting tubing to the chamber such that the rinse liquid passes only in contact with surfaces that have been microbially decontaminated, whereby the rinse liquid is prevented from carrying microbial contamination to the item.

In a second aspect the invention provides a microbial decontamination apparatus which comprises: a chamber (20) for receiving an item to be decontaminated with a strong oxidant solution;

a pre-measured dose of dry reagents which when dissolved in water produces a strong oxidant solution;

a receiving region (34) for receiving the pre-measured dose;

a pump (50) for selectivelypumping the strong oxidant solution to the chamber;

interconnecting tubing for interconnecting the dry reagent-receiving region (34) with the pump, the chamber, and a water supply (10), whereby water from the water supply can selectively flow through the reagent-receiving region (34) and intermix with the dry reagents to form the strong oxidant solution and such that the pump selectively circulates the strong oxidant solution through the chamber (20).

In accordance with a more limited aspect of the present invention, the powdered reagents include a water-soluble acid precursor and a water-soluble peroxy compound and the dilutant includes water.

In accordance with a yet more limited aspect of the present invention the acid precursor includes acetylsalicylic acid and the persalt includes sodium perborate in appropriate concentrations to produce a peracetic acid solution in a concentration of0.2% w/v.

In accordance with another aspect of the present invention, a premeasured sealed vial of antimicrobial concentrate is provided. The vial contains a water soluble acid precursor and a water soluble peroxy compound which, when mixed with water, produce a strong oxidant peracetic acid and buffer solution.

In accordance with a more limited aspect of the present invention, the acid precursor is a acetylsalicylic acid and the peracid is sodium perborate which results in a peracetic acid peroxy compound and buffer solution.

One advantage of the present invention is that it is stable during shipping and handling. No special venting is required.

Another advantage of the present invention is that it provides an anti-microbial agent which quickly sterilizes or disinfects medical equipment or the like.

Another advantage of the present invention is that it works on substantially all materials with minimal corrosion.

Yet another advantage of the present invention is that it facilitates automated sterilizing and minimizes

the opportunity for operator error.

Brief Description of the Drawings

There are now described, by way of example and with reference to the accompanying drawings, preferred embodiments of the method and apparatus of the invention. The invention may take form in various components and arrangements of components or in various steps and arrangements of steps. The drawings are only for purposes of illustrating a preferred embodiment and are not to be construed as limiting the invention.

In the drawings:

FIGURE 1 is a perspective view of a sterilizing apparatus in accordance with the present invention; and

FIGURE 2 is a tubing diagram of the sterilizer of FIGURE 1.

Detailed Description of the Preferred Embodiments

With reference to FIGURES 1 and 2, a dilutant or water source **10** supplies water or other fluid reagents. In the preferred sterilizer embodiment, the water source includes a length of tubing **12** connected with a water spigot or other building plumbing and a control valve **14** for selectively preventing and permitting the flow of water to a sterilizing means **16**. In the preferred embodiment, the sterilizing means is a filter which removes particles which are as large or larger than bacteria. Thermal, chemical, radiological, and other conventional water sterilizing means are also contemplated. Optionally, an in-line water treatment means may be provided for modifying the chemical composition of the water. For example, a water softening cartridge may be provided for reducing or eliminating calcium and magnesium salts from the water. Alternately, various water treatments may be added to the water, such as a wetting agent, a sequestering agent, or others of the reagents to be discussed herein below.

A tubing system **18** connects the filter or other sterilizing means **16** with a basin or other means **20** for receiving an item to be sterilized. In the preferred embodiment, the basin receives a removable container or tray **22** configured in accordance with the item to be sterilized, e.g. an endoscope. The container may have appropriate liquid ports, vents, sterilant distribution system, medical instrument positioners and retainers, closures, etc. such that instruments can be sterilized, rinsed, and stored within the container without opening the container. A lid **24** is sealed to the basin in a lowered position by a resilient gasket **26**. Optionally, a transparent window **28** is defined in the lid.

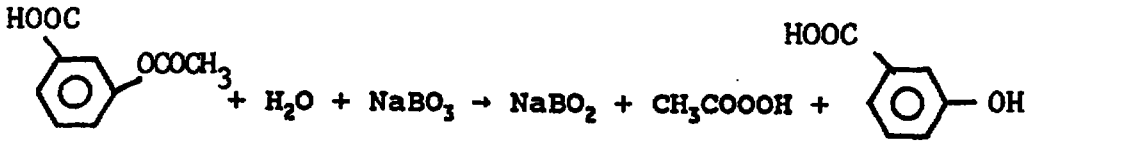
The tubing system **18** includes a basin inlet **30** for filling the basin to surround the items with a sterilant solution and a basin drain **32**. A reagent receiving well **34** collects the fluid from the filled basin. Vent lines **36** enable air to be vented from the container and basin such that they are completely filled with the sterilant solution, rinse water, or other liquids. Any excess fluid is discharged through check valve **38** into a drain line **40**.

A sealed ampule **42** with a premeasured dose of dry ingredients that form corrosion inhibitors and anti-microbial agents when mixed with water is emptied into the well **34**. Optionally, two compartments may be provided such that the corrosion inhibitors are introduced and circulated first over the item to be sterilized or disinfected. This provides corrosion protection before the corrosive anti-microbial agent contacts the item. In the preferred embodiment, the corrosion inhibitors and anti-microbial agent reach the item contemporaneously. As described in greater detail below, the powdered water-soluble reagents include compositions when mixed with water or a water-based solution, form a strong oxidant or other antimicrobial agent. The reagents further provide buffers and anticorrosive agents. More specifically to the preferred embodiment, the dry ingredients include a water-soluble acid precursor and a water-soluble persalt which, when dissolved in water, form a peracetic acid solution with an anti-microbially effective concentration of peracetic acid. Moreover, the water soluble acid precursor and water soluble peracid react or are mixed with other ingredients to provide a buffer, e.g. a borate, for bringing the pH to a neutral level and to inhibit steel corrosion. Other corrosion inhibitors, such as a molybdate for inhibiting aluminum and steel corrosion, a triazole for inhibiting copper and brass corrosion, and the like are optionally included in the powdered ingredients. Wetting and sequestering agents may also be included in the dry ingredients.

The operator closes the lid **24** and the system is filled with water. A pump **50** selectively draws solution or water from the basin **20** through well **34** and returns it to the basin inlet **30**. The water dissolves the powdered reagents allowing them to react, forming the antimicrobial solution. Preferably, the vent line **36** is very short and of a substantial diameter such that the solution is circulated over exposed surfaces of the drain check valve **38** and an air sterilizing filter **52**. A heating coil **54** adjusts the temperature of the solution. Recirculation continues until the interior of the medical items and all exposed surfaces of the tubing system, pump, basin, container, and valves are sterilized. Alternately, once fully dissolved and distributed the sterilant may remain quiescent without further circulation for a selected duration.

After the preselected sterilization or disinfecting period, the antimicrobial solution is drained through a drain valve **56**. Sterile air is drawn into the system through the air sterilizing filter **52** that removes any particles the size of a bacteria or larger. The fill valve **14** is opened and the drain valve **56** is closed such that the sterile filter **16** provides a source of sterile rinse. Note that the sterile rinse liquid flows only in contact with sterilized surfaces of the tubing system and valves in order to assure sterility. Every tubing and valve surface from the filter **16** to the drain has been exposed to the circulating antimicrobial solution for a sufficient duration to assure that it is microbial contamination-free. The pump **50** circulates the sterile rinse through the system for a selected duration sufficient to rinse any deposits or residue, such as salts, that strong buffered solutions tend to deposit. At the end of the rinse cycle, the rinse solution is drained by opening the drain valve **56**. When a return valve **60** is closed, the pump **50** pumps liquid from the system out the drain valve **56**. Additional drain lines (not shown) and aspirators or pumps (not shown) may be provided for removing liquids from every region of the system. The exact location of such additional drains will be dependent on the bends and contours of the plumbing system.

In the preferred embodiment, the ampule contains acetylsalicylic acid (acid precursor) and sodium perborate (persalt). The relative amounts of these two additives are selected so as to produce the chemical reaction:



Acetylsalicylic acid	Sodium Perborate	Sodium Metaborate	Peracetic acid	Salicylic Acid

The total volume of dry ingredients is such that the resultant water solution has a concentration of peracetic acid of 0.2% w/v - a biocidally effective concentration. The Sodium Metaborate ($NaBO_2$) is an inorganic corrosion inhibitor and the Salicylic acid is an organic corrosion inhibitor with a benzoate function. Preferably, an additional powdered water-soluble phosphate is also present in the ampule to provide additional corrosion resistance when dissolved by the water. The chemical formulation of the phosphate is preferably selected such that it is inert relative to the above described chemical reaction, or at least does not interfere with the chemical reactions formation of peracetic acid and corrosion inhibitors.

A 0.2% w/v peracetic acid solution and associated corrosion inhibitors generated by the above chemical reaction is anti-microbially effective with twelve minutes exposure at 50°C even to Clostridium sporgenes inoculum on a penicylinders carrier, the carrier and inoculum most resistant to peroxyacetic acid. Antimicrobial test results are summarized in Table 1 below in which each test was conducted at 50°C with twelve minutes exposure and the peracetic acid at 0.2% w/v.

Other oxidizing or antimicrobial agents can also be generated in situ, such as chlorine dioxide, chlorine, hydrogen peroxide, and mixtures thereof. More specifically, potassium chromates, sodium chloride, and phosphates may be mixed according to the following equation to produce a strong chlorine oxidant on the addition of water:

$$K_2Cr_2O_7 + 6\,NACl + 7\,H_3PO_4 \rightarrow 4\,K_2HPO_4 + Cr_2N(HPO_4)_3 + HOCl + 6H^+ + H_2O$$

Optionally, excess dichromate and an organic corrosion inhibitor may be provided for improved buffering and corrosion inhibiting.

Hydrogen peroxide and an inorganic inhibitor can be generated:

$$NaBO_3 + H_2O + H_3PO_4 \rightarrow H_2O_2 + NaBO_2 + H_3PO_4$$

Similarly, chlorine dioxide can be generated from powdered ingredients on the addition of water:

$$2NaClO_2 + LiClO + H_2O \rightarrow 2ClO_2 + NaOH + NaCl + LiOH$$

A mixed biocide system can be achieved by adding sodium chloride to the peracetic acid reaction to produce hypochlorous acid.

$$CH_3COOOH + Na^+ + Cl^- \rightarrow CH_3COONa + HOCl$$

Excess peracetic acid is deliberately present such that both peracetic acid and hypochlorous acid are present in the biocidal solution.

In these compositions, it is preferable to add additional corrosion inhibitors and buffers to protect copper, brass, aluminum, steel, and the like. Preferably, corrosion inhibitors are added which result in three corrosion inhibitors in the final solution. One is an organic inhibitor, one is an inorganic inhibitor, and the third can be either.

The copper and brass corrosion inhibitors are preferably benzotriazoles and tolytriazoles, which are preferred due to their stability in the presence of strong oxidizing compounds. Mercaptobenzathiozol might also be utilized but is more apt to be oxidized or destabilized by strong oxidizers.

Azoles, benzoates, and other five membered ring compounds may also prove acceptable as copper and brass corrosion inhibitors.

By way of example, the anti-corrosive buffering compounds may include a mixture of phosphate in sufficient volume to produce a final concentration of 1.25% weight per volume and molybdates in an appropriate amount to produce a final solution of .011% weight per volume. Phosphates may also be effective in the range of 0.2% to 12% and the molybdates may be effective from 0.1 to 10%. Optionally, chromates, dichromates, tungstates, vanadates, other borates, and combinations thereof, may be substituted in appropriate concentrations to inhibit steel corrosion, i.e. buffer to a generally neutral pH, and aluminum corrosion.

In hard water, the phosphates tend to cause calcium and magnesium salts to precipitate and coat the instruments being sterilized and parts of the sterilizing system. A sequestering agent appropriate to prevent precipitation, such as sodium hexametaphosphate, may be provided. Of course, if deionized or soft water is utilized the sequestering agent may be eliminated. However, to insure universal applicability with any water that might be utilized, the presence of a sequestering agent is preferred.

A wetting agent present from 0.001 to 1.0% (w/v) improves the wetting of the surface of the instrument by the anti-microbial agent. The wetting agent has also been found to increase penetration of the anti-microbials improving anti-microbial efficacy while reducing corrosion.

The following are examples that illustrate the corrosion inhibiting effectiveness of various strong oxidant anti-microbial formulations. Coupons of 410 stainless steel, brass (ASTM B36-C 2600), aluminum (5052-H 32), and carbon steel scalpel blades were exposed to two changes of sterilant mix for a total of four hours exposure at 50-55°C. One set of coupons was run in distilled water and a sterilant mix (0.5% sodium perborate and 0.5% aspirin) and a second set in tap water and sterilant mix. A second set of tests was performed using brass and aluminum coupons, and carbon steel scalpel blades in a matrix with concentrations of disodium phosphate of 0, 0.2, 0.4, 0.5, and 0.7% and concentrations of benzotriazole of 0, 0.001, 0.005, 0.01, and 0.02%. Each type of coupons were exposed to sterilant mix and additives for three hours at 50-55°C. All coupons were rinsed well with distilled water and acetone and allowed to dry before evaluation.

Corrosion or discoloration was noted on all materials using just the basic peracetic acid, sodium metaborate, and salicylic acid solution. Carbon steel and 410 stainless steel showed only minor corrosion. Aluminum was discolored and showed some pitting. Brass was heavily corroded on most surfaces and showed some pitting. In the matrix, the addition of 0.001% benzotriazole or 0.4% phosphate eliminated corrosion on carbon steel. The addition of 0.4% phosphate eliminated corrosion on aluminum. For brass, the addition of 0.2% phosphate or 0.05% benzotriazole eliminated pitting corrosion. However, phosphate caused darkening of brass which was apparent unless 0.02% benzotriazole was added. Random spotting of brass occurred at all concentrations. This sort of corrosion can be eliminated by adding a surfactant.

The invention has been described with reference to the preferred embodiments. Obviously, modifications and alterations will occur to others upon reading and understanding the preceding detailed description. It is intended that the invention be construed as including all such alterations and modifications insofar as they come within the scope of the appended claims or the equivalents thereof.

The holder holding the reagents can be, for example, a sealed container, for instance a cup or dish which can be of plastics material, having a heat-sealed peel-off top or other closure.

Claims

1. A method of microbially decontaminating an item by immersing the item in an anti-microbial solution formed by reacting a soluble acid precurser and a soluble peracid compound in a dilutant, characterized by:

   (a) measuring preselected amounts of dry reagents including the acid precurser and the peracid;
   (b) packaging the measured dry acid precurser and peracid in a holder and storing the holder until items are to be microbially decontaminated;
   (c) opening the holder and intermixing the dry acid precurser and the dry peracid compound with the dilutant to form the anti-microbial solution; and
   (d) immersing the item in the anti-microbial solution;
   the intermixing and immersing steps including:
   recirculating the anti-microbial solution from a chamber in which the item is disposed through interconnecting tubing and back to the chamber, whereby the interconnecting tubing and chamber in-

The copper and brass corrosion inhibitors are preferably benzotriazoles and tolytriazoles, which are preferred due to their stability in the presence of strong oxidizing compounds. Mercaptobenzathiozol might also be utilized but is more apt to be oxidized or destabilized by strong oxidizers.

Azoles, benzoates, and other five membered ring compounds may also prove acceptable as copper and brass corrosion inhibitors.

By way of example, the anti-corrosive buffering compounds may include a mixture of phosphate in sufficient volume to produce a final concentration of 1.25% weight per volume and molybdates in an appropriate amount to produce a final solution of .011% weight per volume. Phosphates may also be effective in the range of 0.2% to 12% and the molybdates may be effective from 0.1 to 10%. Optionally, chromates, dichromates, tungstates, vanadates, other borates, and combinations thereof, may be substituted in appropriate concentrations to inhibit steel corrosion, i.e. buffer to a generally neutral pH, and aluminum corrosion.

In hard water, the phosphates tend to cause calcium and magnesium salts to precipitate and coat the instruments being sterilized and parts of the sterilizing system. A sequestering agent appropriate to prevent precipitation, such as sodium hexametaphosphate, may be provided. Of course, if deionized or soft water is utilized the sequestering agent may be eliminated. However, to insure universal applicability with any water that might be utilized, the presence of a sequestering agent is preferred.

A wetting agent present from 0.001 to 1.0% (w/v) improves the wetting of the surface of the instrument by the anti-microbial agent. The wetting agent has also been found to increase penetration of the anti-microbials improving anti-microbial efficacy while reducing corrosion.

The following are examples that illustrate the corrosion inhibiting effectiveness of various strong oxidant anti-microbial formulations. Coupons of 410 stainless steel, brass (ASTM B36-C 2600), aluminum (5052-H 32), and carbon steel scalpel blades were exposed to two changes of sterilant mix for a total of four hours exposure at 50-55°C. One set of coupons was run in distilled water and a sterilant mix (0.5% sodium perborate and 0.5% aspirin) and a second set in tap water and sterilant mix. A second set of tests was performed using brass and aluminum coupons, and carbon steel scalpel blades in a matrix with concentrations of disodium phosphate of 0, 0.2, 0.4, 0.5, and 0.7% and concentrations of benzotriazole of 0, 0.001, 0.005, 0.01, and 0.02%. Each type of coupons were exposed to sterilant mix and additives for three hours at 50-55°C. All coupons were rinsed well with distilled water and acetone and allowed to dry before evaluation.

Corrosion or discoloration was noted on all materials using just the basic peracetic acid, sodium metaborate, and salicylic acid solution. Carbon steel and 410 stainless steel showed only minor corrosion. Aluminum was discolored and showed some pitting. Brass was heavily corroded on most surfaces and showed some pitting. In the matrix, the addition of 0.001% benzotriazole or 0.4% phosphate eliminated corrosion on carbon steel. The addition of 0.4% phosphate eliminated corrosion on aluminum. For brass, the addition of 0.2% phosphate or 0.05% benzotriazole eliminated pitting corrosion. However, phosphate caused darkening of brass which was apparent unless 0.02% benzotriazole was added. Random spotting of brass occurred at all concentrations. This sort of corrosion can be eliminated by adding a surfactant.

The invention has been described with reference to the preferred embodiments. Obviously, modifications and alterations will occur to others upon reading and understanding the preceding detailed description. It is intended that the invention be construed as including all such alterations and modifications insofar as they come within the scope of the appended claims or the equivalents thereof.

The holder holding the reagents can be, for example, a sealed container, for instance a cup or dish which can be of plastics material, having a heat-sealed peel-off top or other closure.

Claims

1. A method of microbially decontaminating an item by immersing the item in an anti-microbial solution formed by reacting a soluble acid precurser and a soluble peracid compound in a dilutant, characterized by:

   (a) measuring preselected amounts of dry reagents including the acid precurser and the peracid;
   (b) packaging the measured dry acid precurser and peracid in a holder and storing the holder until items are to be microbially decontaminated;
   (c) opening the holder and intermixing the dry acid precurser and the dry peracid compound with the dilutant to form the anti-microbial solution; and
   (d) immersing the item in the anti-microbial solution;
   the intermixing and immersing steps including:
   recirculating the anti-microbial solution from a chamber in which the item is disposed through interconnecting tubing and back to the chamber, whereby the interconnecting tubing and chamber in-

terior are microbially decontaminated together with the item; and

the method including a rinsing step of passing a microbially decontaminated rinse liquid from a source of the rinse liquid through the interconnecting tubing to the chamber such that the rinse liquid passes only in contact with surfaces that have been microbially decontaminated, whereby the rinse liquid is prevented from carrying microbial contamination to the item.

2. A method according to Claim 1, in which the soluble acid precurser comprises acetylsalicylic acid, the soluble peracid comprises sodium perborate and the dilutant is water; and the acetylsalicylic acid and the sodium perborate are dissolved in the water in the intermixing step to form a resultant solution that has at least 0.02% w/v concentration of peracetic acid.

3. A method according to Claim 1, in which the dry reagents comprise any of the following mixtures (a) to (e);
   (a) $K_2Cr_2O_7$, NaCl, and H_3PO_4;
   (b) $NaBO_3$ and H_3PO_4;
   (c) $NaClO_2$ and $LiClO_3$;
   (d) Acetylsalicylic acid and $NaBO_3$; and
   (e) Acetylsalicylic, $NaBO_3$, and NaCl.

4. A method according to any of the preceding claims, in which the dry reagents further include at least one corrosion inhibitor selected from:
   benzotriazoles, tolytriazoles, mercaptobenzathiozol, azoles, benzoates, molybdates, phosphates, chromates, dichromates, tungstates, vanadates, and borates.

5. A method according to any of claims 1-3, in which the dry reagents further include at least one organic corrosion inhibitor selected from:
   benzotriazoles, tolytriazoles, mercaptobenzathiozol, azoles, imidazoles, thiozoles, indoles, pyrazoles, and benzoates;
   and at least one inorganic corrosion inhibitor selected from:
   molybdates, phosphates, chromates, dichromates, tungstates, silicates, vanadates, and borates.

6. A method according to any of the preceding claims, in which the dry reagents are in the form of powders.

7. A method according to any of the preceding claims in which the intermixing is effected mechanically.

8. A method according to any of the preceding claims, in which the intermixing of the acid precurser and peracid compound in the dilutant produces a corrosion inhibitor or a buffering agent.

9. A microbial decontamination apparatus which comprises:
   a chamber (20) for receiving an item to be decontaminated with a strong oxidant solution;
   a pre-measured dose of dry reagents which when dissolved in water produces a strong oxidant solution;
   a receiving region (34) for receiving the pre-measured dose;
   a pump (50) for selectively pumping the strong oxidant solution to the chamber;
   interconnecting tubing for interconnecting the dry reagent-receiving region (34) with the pump, the chamber, and a water supply (10), whereby water from the water supply can selectively flow through the reagent-receiving region (34) and intermix with the dry reagents to form the strong oxidant solution and such that the pump selectively circulates the strong oxidant solution through the chamber (20).

10. An apparatus according to Claim 9, which includes a plurality of disposable holders (42), each holder holding a preselected dose of the dry reagents to be received in the reagent receiving region.

11. An apparatus according to Claim 9 or 10, in which the dry reagents comprise any of the following (a) to (e):
   (a) $K_2Cr_2O_7$, NaCl, and H_3PO_4;
   (b) $NaBO_3$ and H_3PO_4;
   (c) $NaClO_2$ and LiClO;
   (d) Acetylsalicylic acid and $NaBO_3$; and

(e) Acetylsalicylic acid, $NaBO_3$, and NaCl.

12. An apparatus according to Claim 9, 10 or 11,
in which the dry reagents include at least one corrosion inhibitor selected from:
benzotriazoles, tolytriazoles, mercaptobenzathiozol, azoles, imidazoles, thiozoles, indoles, pyrazoles, benzoates, molybdates, phosphates, chromates, silicates, dichromates, tungstates, vanadates, and borates.

13. A cartridge, pack, ampoule, or other holder (42) for use in the method of claim 1 or with the apparatus of claim 9, said holder holding premeasured amounts of reagents such that when the reagents are mixed with a water-containing liquid, there is produced an aqueous solution of a strong oxidant.

14. A holder according to claim 13 whose reagents comprise any of the following mixtures (a) to (e):
(a) $K_2Cr_2O_7$, NaCl, and H_3PO_4;
(b) $NaBO_3$ and H_3PO_4;
(c) $NaClO_2$ and LiClO;
(d) Acetylsalicylic acid and $NaBO_3$; and,
(e) Acetylsalicylic acid, $NaBO_3$, and NaCl.

15. A holder according to claim 13 whose reagents comprise a premeasured dose of powdered acetylsalicylic acid and sodium perborate such that when the powdered reagents are mixed with water, a peracetic acid anti-microbial agent and sodium metaborate and salicylic acid corrosion inhibitors are formed and dissolve in the water to form a corrosion-inhibiting anti-microbial solution for one cycle of an automated microbial decontaminating apparatus.

16. A holder according to claim 13, 14 or 15, which includes also at least one corrosion inhibitor selected from:
benzotriazoles, tolytriazoles, mercaptobenzathiozol, azoles, imidazoles, thiozoles, indoles, pyrazoles, benzoates, molybdates, phosphates, chromates, silicates, dichromates, tungstates, vanadates, and borates.

Patentansprüche

1. Ein Verfahren zum mikrobischen Dekontaminieren eines Gegenstandes durch Eintauchen des Gegenstandes in eine antimikrobische Lösung, welche durch Raktion eines löslichen Säurevorläufers und einer löslichen Persäureverbindung in einem Lösungsmittel gebildet worden ist, **gekennzeichnet durch:**
(a) Abmessen vorgewählter Mengen trockener Reagenzien, welche den Säurevorläufer und die Persäure enthalten;
(b) Verpacken des abgemessenen trockenen Säurevorläufers und der Persäure in einem Halter und Lagern des Halters, bis Gegenstände mikrobisch zu dekontaminieren sind;
(c) Öffnen des Halters und Vermischen des trockenen Säurevorläufers und der trockenen Persäureverbindung mit dem Lösungsmittel, um die antimikrobische Lösung zu bilden; und
(d) Eintauchen des Gegenstandes in die antimikrobische Lösung; wobei die Schritte des Vermischens und des Eintauchens folgendes einschließen:
Rezirkulieren der antimikrobischen Lösung von einer Kammer, in welcher der Gegenstand angeordnet ist durch Verbindungsrohre und zurück zu der Kammer, wodurch die Verbindungsrohre und das Kammerinnere zusammen mit dem Gegenstand mikrobisch dekontaminiert werden; und
wobei einen das Verfahren einen Spülschritt durch Vorbeiführen einer mikrobisch dekontaminerten Spülflüssigkeit von einer Quelle der Spülflüssigkeit durch die Verbindungsrohre zu der Kammer einschließt, so daß die Spülflüssigkeit nur in Berührung mit Oberflächen kommt, welche mikrobisch dekontaminiert worden sind, wodurch verhindert wird, daß die Spülflüssigkeit mikrobische Verunreinigungen zu dem Gegenstand trägt.

2. Ein Verfahren nach Anspruch 1, bei welchem der lösbare Säurevorläufer Acetylsalicylsäure enthält, die lösbare Persäure Natriumperborat enthält und das Lösungsmittel Wasser ist; und die Acetylsalicylsäure und das Natriumperborat in dem Wasser bei dem Schritt des Vermischens aufgelöst werden, um eine resultierende Lösung zu bilden, welche wenigstens eine Konzentration von 0,02% w/v (= 0,02g in 100 ml) von Peressigsäure hat.

* C L M S *

3. Ein Verfahren nach Anspruch 1, bei welchem die trocknen Reagenzien eine der folgenden Mischungen (a) bis (e) enthalten;
   (a) $K_2Cr_2O_7$, NaCl, und H_3PO_4;
   (b) $NaBO_3$ und H_3PO_4;
   (c) $NaClO_2$ und $LiClO_3$;
   (d) Acetylsalicylsäure und $NaBO_3$; und
   (e) Acetylsalicylsäure, $NaBO_3$, und NaCl.

4. Ein Verfahren nach einem der vorherigen Ansprüche, bei welchem die trockenen Reagenzien weiterhin wenigstens ein korrosionshemmendes Mittel aus folgenden ausgewählt enthalten:
Benzotriazole, Tolytriazole, Mercaptobenzothiazol, Azole, Benzoate, Molybdate, Phosphate, Chromate, Dichromate, Wolframate, Vanadate, und Borate.

5. Ein Verfahren nach einem der Ansprüche 1 bis 3, bei welchem die trockenen Reagenzien außerdem wenigstens ein organisches korrosionshemmendes Mittel enthalten, welches ausgewählt ist aus:
Benzotriazole, Tolytriazole, Mercaptobenzothiazol, Azole, Imidazole, Thiazole, Indole, Pyrazole, und Benzoate; und wenigstens ein anorganisches korrosionshemmendes Mittel ausgewählt aus:
Molybdate, Phosphate, Chromate, Dichromate, Wolframate, Silikate, Vanadate, und Borate.

6. Ein Verfahren nach einem der vorhergehenden Ansprüche, bei welchem die trocknen Reagenzien pulverförmig sind.

7. Ein Verfahren nach einem der vorhergehenden Ansprüche, bei welchem das Vermischen mechanisch ausgeführt wird.

8. Ein Verfahren nach einem der vorhergehenden Ansprüche, bei welchem das Vermischen des Säurevorläufers und der Persäureverbindung in dem Lösungsmittel ein korrosionshemmendes Mittel oder ein Pufferagens erzeugt.

9. Eine Vorrichtung zum mikrobischen Dekontaminieren, welche enthält:
Eine Kammer (20) zur Aufnahme eines mit einer stark oxidierenden Lösung zu dekontaminierenden Gegenstandes;
eine vorabgemessene Dosis von trockenen Reagenzien, welche aufgelöst in Wasser eine stark oxidierende Lösung erzeugen; einen Aufnahmebereich (34) zur Aufnahme der vorabgemessenen Dosis;
eine Pumpe (50) zum wahlweisen Pumpen der stark oxidierenden Lösung in die Kammer;
Verbindungsrohre zum Miteinanderverbinden des die trockenen Reagenzien aufnehmenden Bereiches (34) mit der Pumpe, der Kammer, und einer Wasserversorgung (10), wodurch Wasser von der Wasserversorgung wahlweise durch den reagenzaufnehmenden Bereich (34) fließen und sich mit den trockenen Reagenzien vermischen kann, um die stark oxidierende Lösung zu bilden, und derart, daß die Pumpe wahlweise die stark oxidierende Lösung durch die Kammer (20) zirkulieren läßt.

10. Eine Vorrichtung nach Anspruch 9, welche eine Vielzahl von Einweghaltern (42) enthält, wobei jeder Halter eine vorgewählte Dosis der trockenen Reagenzien hält, welche in dem reagenzaufnehmenden Bereich aufgenommen werden soll.

11. Eine Vorrichtung nach Anspruch 9 oder 10, bei welcher die trocknen Reagenzien eines aus den folgenden (a) bis (e) enthalten:
   (a) $K_2Cr_2O_7$, NaCl, und H_3PO_4;
   (b) $NaBO_3$ und H_3PO_4;
   (c) $NaClO_2$ und LiClO;
   (d) Acetylsalicylsäure und $NaBO_3$; und
   (e) Acetylsalicylsäure, $NaBO_3$ und NaCl.

12. Eine Vorrichtung nach Anspruch 9, 10 oder 11, bei welcher die trocknen Reagenzien wenigstens ein korrosionshemmendes Mittel aus folgenden ausgewählt enthalten:
Benzotriazole, Tolytriazole, Mercaptobenzothiazol, Azole, Imidazole, Thiazole, Indole, Pyrazole, Benzoate, Molybdate, Phosphate, Chromate, Silikate, Dichromate, Wolframate, Vanadate, und Borate.

13. Eine Patrone, Packung, Ampulle oder ein anderer Halter (42) zur Verwendung in dem Verfahren nach An-

* C L M S *

spruch 1 oder bei der Vorrichtung nach Anspruch 9, wobei der Halter eine vorabgemessene Menge von Reagenzien hält, so daß, wenn die Reagenzien mit einer wasserenthaltenden Flüssigkeit gemischt werden, eine wässrige Lösung eines starken Oxidationsmittels erzeugt wird.

14. Ein Halter nach Anspruch 13, dessen Reagenzien eine der folgenden Mischungen (a) bis (e) enthalten:
    (a) $K_2Cr_2O_7$, NaCl, und H_3PO_4;
    (b) $NaBO_3$ und H_3PO_4;
    (c) $NaClO_2$ und LiClO;
    (d) Acetylsalicylsäure und $NaBO_3$; und,
    (e) Acetylsalicylsäure, $NaBO_3$, und NaCl.

15. Ein Halter nach Anspruch 13, dessen Reagenzien eine vorabgemessene Dosis von pulverisierter Acetylsalicylsäure und Natriumperborat derart enthalten, daß, wenn die pulverisierten Reagenzien mit Wasser gemischt werden, ein antimikrobisch wirkendes Peressigsäureagens und Natriummetaborat- und Salicylsäure-Korrosionshemmer bilden und sich in dem Wasser lösen, um eine korrosionshemmende antimikrobische Lösung für einen Arbeitscyclus einer automatischen Vorrichtung zum mikrobischen Dekontaminieren zu bilden.

16. Ein Halter nach Anspruch 13, 14 oder 15, welcher auch wenigstens ein korrosionshemmendes Mittel ausgewählt aus folgenden enthält:
    Benzotriazole, Tolytriazole, Mercaptobenzothiazol, Azole, Imidazole, Thiazole, Indole, Pyrazole, Benzoate, Molybdate, Phosphate, Chromate, Silikate, Dichromate, Wolframate, Vanadate, und Borate.

Revendications

1. Procédé de décontamination microbienne d'un objet en immergeant l'objet dans une solution antimicrobienne obtenue en faisant réagir un précurseur acide soluble et un composé peracide soluble, dans un diluant, caractérisé par :
    (a) la mesure de quantités présélectionnées de réactifs secs comprenant le précurseur acide et le peracide;
    (b) le placement du précurseur acide sec et du peracide mesurés dans un récipient et le stockage du récipient jusqu'à ce que des objets doivent subir une décontamination microbienne;
    (c) l'ouverture du récipient et le mélange du précurseur acide sec et du peracide sec avec le diluant pour former la solution antimicrobienne; et
    (d) l'immersion de l'objet dans la solution antimicrobienne;
    les étapes de mélange et d'immersion comprenant la recirculation de la solution antimicrobienne depuis une chambre dans laquelle est placé l'objet par des tuyauteries d'interconnexion avec retour à la chambre, les tuyauteries d'interconnexion et l'intérieur de la chambre subissant une décontamination microbienne en même temps que l'objet, et
    le procédé comprenant une étape de rinçage consistant à faire passer un liquide de rinçage ayant subi une décontamination microbienne et provenant d'une source de liquide de rinçage, à travers les tuyauteries d'interconnexion vers la chambre, de façon que le liquide de rinçage soit uniquement en contact avec des surfaces qui ont subi une décontamination microbienne, le liquide de rinçage ne pouvant pas de ce fait provoquer une contamination microbienne de l'objet.

2. Procédé selon la revendication 1, dans lequel le précurseur acide soluble comprend de l'acide acétylsalicylique, le peracide soluble comprend du perborate de sodium et le diluant est de l'eau, et l'acide acétylsalicylique et le perborate de sodium sont dissous dans l'eau au cours de l'étape de mélange pour former une solution résultante ayant une concentration d'au moins 0,02% poids/ volume d'acide peracétique.

3. Procédé selon la revendication 1, dans lequel les réactifs secs comprennent l'un quelconque des mélanges ci-après (a) à (e);
    (a) $K_2Cr_2O_7$, NaCl, et H_3PO_4;
    (b) $NaBO_3$ et H_3PO_4;
    (c) $NaClO_2$ et $LiClO_3$;
    (d) Acide acétylsalicylique et $NaBO_3$; et

(e) Acide acétylsalicylique, $NaBO_3$ et NaCl.

4. Procédé selon l'une quelconque des revendications précédentes, dans lequel les réactifs secs comprennent en outre au moins un inhibiteur de corrosion choisi parmi les benzotriazoles, les tolytriazoles, le mercaptobenzathiozole, les azoles, les benzoates, les molybdates, les phosphates, les chromates, les dichromates, les tungstates, les vanadates et les borates.

5. Procédé selon l'une quelconque des revendications 1 à 3, dans lequel les réactifs secs comprennent en outre au moins un inhibiteur de corrosion organique choisi parmi les benzotriazoles, les tolytriazoles, le mercaptobenzathiozole, les azoles, les imidazoles, les thiozoles, les indoles, les pyrazoles et les benzoates ;

et au moins un inhibiteur de corrosion inorganique choisi parmi les molybdates, les phosphates, les chromates, les dichromates, les tungstates, les silicates, les vanadates et les borates.

6. Procédé selon l'une quelconque des revendications précédentes, dans lequel les réactifs secs se présentent sous forme de poudres.

7. Procédé selon l'une quelconque des revendications précédentes, dans lequel le mélange est effectué mécaniquement.

8. Procédé selon l'une quelconque des revendications précédentes, dans lequel le mélange du précurseur acide et du composé peracide dans le diluant fournit un inhibiteur de corrosion ou un agent de tamponnage.

9. Appareil de décontamination antimicrobienne comprenant

une chambre (20), destinée à recevoir un objet à décontaminer par une solution fortement oxydante;

une dose prédéterminée de réactifs secs qui, par dissolution dans l'eau, permettent d'obtenir une solution fortement oxydante;

une zone de réception (34) destinée à recevoir la dose prédéterminée;

une pompe (50) pour pomper sélectivement la solution fortement oxydante vers la chambre;

des tuyauteries d'interconnexion pour interconnecter la zone de réception des réactifs secs (34) avec la pompe, la chambre et une alimentation d'eau (10), l'eau provenant de l'alimentation d'eau pouvant s'écouler sélectivement à travers la zone de réception des réactifs (34) et se mélanger avec les réactifs secs pour former la solution fortement oxydante, et ceci de façon que la pompe fasse circuler sélectivement la solution fortement oxydante à travers la chambre (20).

10. Appareil selon la revendication 9, comprenant plusieurs récipients à jeter (42), chaque récipient contenant une dose prédéterminée des réactifs secs à placer dans la zone de réception des réactifs.

11. Appareil selon la revendication 9 ou 10, dans lequel les réactifs secs comprennent l'un quelconque des mélanges mentionnés ci-après (a) à (e) :

(a) $K_2Cr_2O_7$, NaCl, et H_3PO_4;
(b) $NaBO_3$ et H_3PO_4;
(c) $NaClO_2$ et LiClO;
(d) Acide acétylsalicylique et $NaBO_3$; et
(e) Acide acétylsalicylique, $NaBO_3$ et NaCl.

12. Appareil selon la revendication 9, 10 ou 11, dans lequel les réactifs secs comprennent au moins un inhibiteur de corrosion choisi parmi les benzotriazoles, les tolytriazoles, le mercaptobenzathiozole, les azoles, les imidazoles, les thiozoles, les indoles, les pyrazoles, les benzoates, les molybdates, les phosphates, les chromates, les silicates, les dichromates, les tungstates, les vanadates et les borates.

13. Cartouche, emballage, ampoule ou autre récipient (42) à utiliser pour le procédé de la revendication 1 ou avec l'appareil de la revendication 9, ledit récipient contenant des quantités prédéterminées de réactifs de façon que, par mélange des réactifs avec un liquide aqueux, on obtienne une solution aqueuse d'un oxydant fort.

14. Récipient selon la revendication 13, dont les réactifs comprennent l'un quelconque des mélanges ci-après

* C L M S *

(a) à (e) :
(a) $K_2Cr_2O_7$, NaCl, et H_3PO_4;
(b) $NaBO_3$ et H_3PO_4;
(c) $NaClO_2$ et LiClO;
(d) Acide acétylsalicylique et $NaBO_3$; et
(e) Acide acétylsalicylique, $NaBO_3$ et NaCl.

15. Récipient selon la revendication 13, dont les réactifs comprennent une dose prédéterminée d'acide acétylsalicylique et de perborate de sodium en poudre de façon que, par mélange des réactifs en poudre avec de l'eau, on obtienne un agent antimicrobien formé d'acide peracétique et du métaborate de sodium et que des inhibiteurs de corrosion à base d'acide acétylsalicylique soient formés et se dissolvent dans l'eau pour former une solution antimicrobienne inhibant la corrosion pour un cycle d'un appareil de décontamination antimicrobien automatisé.

16. Récipient selon la revendication 13, 14 ou 15, comprenant au moins un inhibiteur de corrosion choisi parmi les benzotriazoles, les tolytriazoles, le mercaptobenzathiozole, les azoles, les imidazoles, les thiozoles, les indoles, les pyrazoles, les benzoates, les molybdates, les phosphates, les chromates, les silicates, les dichromates, les tungstates, les vanadates et les borates.