Candidate Disinfectants for Research International Products [(1)]

Introduction

To minimize carry-over contamination from run-to-run, it is necessary that an effective cleaning procedure be developed based on the disinfectant of choice or necessity. Disinfectant effectiveness depends on many factors. These include:

- Type of contaminating microorganism or substance – It is more difficult to remove or destroy residual nucleic acids than to kill the microbes those nucleic acids resided in (see also Appendix 1).
- Degree of contamination – This determines the quality of disinfectant required and time of exposure.
- Chemical nature of disinfectant – It is important to understand the mode of action in order to select the appropriate disinfectant.
- Contact time and temperature – Sufficient time and appropriate temperature must be allowed for action of the disinfectant and may depend on the degree of contamination and organic matter load.
- Concentration and quantity of disinfectant – It is important to choose the proper concentration and quantity of disinfectant best suited to each situation. RI can make general recommendations, but it is often best to develop a custom procedure that reflects the specific application and what levels of carry-over are important.
- Amount of proteinaceous material present – High protein based materials absorb and neutralize some chemical disinfectants.
- Presence of organic matter and other compounds such as soaps may neutralize some disinfectants.
- Residual activity and their effect on plastics and metals should be considered. Residues may also generate false negative results in subsequent tests.
- Application temperature, pH and interactions with other compounds must be considered.
- Relative safety to people that may be exposed.

Notes:

1. Selected excerpts from the British Columbia Centre for Disease Control's Brochure, "*Selection and use of Disinfectants*." The entire document can be reviewed on their web site at www.bccdc.ca.

Research International's air samplers are generally compatible with at least short exposures to:

- Detergents,
- Ethyl and isopropyl alcohols,
- Hypochlorite solutions,
- Hydrogen peroxide,
- Ethylene oxide, and
- Formaldehyde
- The top half of the SASS 3010 may be steam sterilized at 121°C

Some disinfectants such as hypochlorite solution are corrosive towards aluminum and other metals, but practically, corrosion is negligible as long as the disinfecting agent is flushed out well or not left in the device for several hours.

Most disinfectants are potentially hazardous. Hypochlorite solutions can release chlorine when mixed with acid; hydrogen peroxide can damage eye membranes; ethylene oxide is flammable and toxic; and formaldehyde is toxic and carcinogenic. The following material is provided as a starting point from which to develop a decontamination protocol that meets your specific needs.

CAUTION: Air samplers process large amounts of air. Volatile and potentially health-threatening components of a disinfecting solution can be rapidly extracted and discharged into surrounding air by an operating sampler.

1.0 Intermediate Level Disinfectants

1.1 Alcohols

In the healthcare setting, "alcohol" refers to two water-soluble chemicals: ethyl alcohol and isopropyl alcohol. These alcohols are rapidly bactericidal rather than bacteriostatic against vegetative forms of bacteria (Gram + and Gram -); they also are tuberculocidal, fungicidal, and virucidal against enveloped viruses. Alcohols are not effective against bacterial spores and have limited effectiveness against nonenveloped viruses. Their cidal activity drops sharply when diluted below 50% concentration and the optimum bactericidal concentration is in the range of 60-90% solutions in water (volume/volume). The antimicrobial activity of alcohols can be attributed to their ability to denature proteins. Higher concentrations are less effective as the action of denaturing proteins is inhibited without the presence of water.

Alcohols are commonly used as topical antiseptics. They are also used to disinfect the surface of medical equipment. Alcohols require time to work and they may not penetrate organic material. The shortcoming of alcohols with respect to Research International's instruments are their tendency to cause rubber and certain plastic tubing to swell and harden

after prolonged and repeated use. Alcohols are flammable and consequently must be stored in a cool, well-ventilated area. They also evaporate rapidly making extended exposure time difficult to achieve unless the items are immersed. Alcohol irritates tissues.

The use of either ethyl alcohol or isopropyl alcohol in a 60-90% solution has recently gained wide acceptance in health care settings as hand antiseptics. They can be used as a reasonable substitute for hand washing as long as hands are not visibly soiled. The drying effect of alcohols on the hands can be counteracted with the addition of emollients and skin conditioning agents to the formulation. Further study is needed to determine the ideal formulation of alcohol based hand antiseptics for effectiveness.

1.2 Hypochlorites

Hypochlorites are the most widely used of the chlorine disinfectants and are available in a liquid (e.g. sodium hypochlorite) or solid (e.g. calcium hypochlorite, sodium dichloroisocyanurate) form. The most common chlorine products in are aqueous solutions of 4 to 6% sodium hypochlorite, which are readily available as “household bleach”. They have a broad spectrum of antimicrobial activity, are unaffected by water hardness, are inexpensive and fast acting, and have a low incidence of serious toxicity. The exact method by which free chlorine destroys microorganisms has not been elucidated. Sodium hypochlorite at the concentration used in household bleach (4-6%) may produce skin and ocular irritation or oropharygeal, esophageal, and gastric burns. Other disadvantages of hypochlorites include corrosiveness to metals in high concentrations (>500 ppm), inactivation by organic matter, discoloring or “bleaching” of fabrics, and release of toxic chlorine gas when mixed with ammonia or acid.

Hypochlorites can eliminate both enveloped and nonenveloped viruses if used in correct dilution and contact time. They are also effective against fungi, bacteria, and algae but not spores. Household bleach is typically diluted using 1:50 with water (1000ppm) for surface disinfection. Bleach solutions have been recommended for use in both hospitals and the community as disinfecting solutions. They are included in most recommendations for decontamination of hepatitis and AIDS viruses. Hypochlorites are also the agent of choice in disinfecting surfaces used for food preparation or in bathrooms. Organic material such as feces or blood inactivate chlorine based disinfectants, therefore, surfaces must be clean before their use. In order to obtain maximum effectiveness with chlorine based disinfectants they must remain in contact with surfaces for several minutes. Chlorine based disinfectants diluted in tap water have a limited shelf life. After 30 days such solutions stored in a polyethylene container will lose 40-50% of their concentration. Ideally solutions used for surface disinfection should be mixed fresh to ensure adequate levels of chlorine for antimicrobial activity.

1.3 Iodine and Iodophor Disinfectants

Iodine and iodophors are well-established chemical disinfectants. These compounds have been incorporated in time release formulations and in soaps (surgical scrubs). Simple iodine tinctures (dissolved in alcohol) have limited cleaning ability. These compounds are bactericidal, sporicidal, virucidal and fungicidal but require a prolonged contact time. The disinfective ability of iodine, like chlorine, is neutralized in the presence of organic material

and hence frequent applications are needed for thorough disinfection. Iodine tinctures can be very irritating to tissues, can stain fabric and be corrosive. "Tamed" iodines such as surgical scrubs and surgical antiseptics generally do not irritate tissues. Besides their use as an antiseptic, iodophors have been used for the disinfection of blood culture bottles and medical equipment such as hydrotherapy tanks, thermometers, and endoscopes. Antiseptic iodophor preparations are not suitable for use as hard-surface disinfectants because of concentration differences. Iodophors formulated as antiseptics contain less free iodine than those formulated as disinfectants.

2.0 HIGH LEVEL DISINFECTANTS

2.1 Hydrogen Peroxide

Peroxides such as hydrogen peroxide are often used as antiseptics to clean wounds. The activity of peroxides is greatest against anaerobic bacteria. Hydrogen peroxide at high concentrations is in some cases is damaging to tissues, resulting in a prolonged healing time. It is useful for cleaning surgical sites after closure, but must be used sparingly to avoid penetrating suture lines, which would inhibit healing.

Stabilized hydrogen peroxides can be used to disinfect environmental surfaces. The literature contains several accounts of the properties, germicidal effectiveness, and potential uses for stabilized hydrogen peroxide in the hospital setting. Stabilized hydrogen peroxides are effective against a broad range of pathogens including both enveloped and nonenveloped viruses, vegetative bacteria, fungi and bacterial spores. Manufacturer’s findings demonstrate that this solution sterilizes in 30 minutes and provides high-level disinfection in 5 minutes. This product has not been used long enough to evaluate material compatibility to endoscopes and other semicritical devices, and further assessment by instrument manufacturers should be done.

Stabilized peroxides may also be blended with iodophors or quaternary ammonia. Hydrogen peroxide is also blended with peracetic acid in high concentrations for use as a high-level disinfectant.

2.2 Gluteraldehyde

Aldehydes have a wide germicidal spectrum. Gluteraldehydes are bactericidal, virucidal, fungicidal, sporicidal and parasiticidal. They are used as a disinfectant or sterilant in both liquid and gaseous forms. They have moderate residual activity and are effective in the presence of limited amounts of organic material. Gluteraldehydes are very potent disinfectants, which can be highly toxic. Use them only as a last resort and then under trained supervision in a well-ventilated setting and with appropriate personal protective equipment.

2.3 Formaldehyde

Formaldehyde is used as a disinfectant and sterilant both in the liquid and gaseous states. Formaldehyde is sold and used principally as a water-based solution called formalin, which is 37% formaldehyde by weight. The aqueous solution is bactericidal, tuberculocidal, fungicidal, virucidal and sporicidal.

Formaldehyde should be handled in the workplace as a potential carcinogen with an employee exposure standard that limits an 8-hour time-weighted average exposure to a concentration of 0.75 ppm. For this reason, employees should have limited direct contact with formaldehyde and these considerations limit its role in sterilization and disinfection processes.

A wide range of microorganisms is destroyed by varying concentrations of aqueous formaldehyde solutions. Although formaldehyde-alcohol is a chemical sterilant and formaldehyde is a high-level disinfectant, the hospital uses of formaldehyde are limited by its irritating fumes and the pungent odor that is apparent at very low levels (<1 ppm).

2.4 Ortho-phthalaldehyde

Ortho-phthalaldehyde (OPA) is a chemical sterilant similar to gluteraldehyde with similar antimicrobial activity. OPA has several potential advantages compared to gluteraldehyde. It has excellent stability over a wide pH range (pH 3-9), is not a known irritant to the eyes and nasal passages, does not require exposure monitoring, has a barely perceptible odor, and requires no activation. OPA, like gluteraldehyde, has excellent material compatibility. A potential disadvantage of OPA is that it stains proteins gray (including unprotected skin) and thus must be handled with caution. However, skin staining would indicate improper handling that requires additional training and/or personal protective equipment (PPE) (gloves, eye and mouth protection, fluid-resistant gowns). Although OPA does not smell, PPE should be worn when handling contaminated instruments, equipment, and chemicals and good ventilation should be provided. In addition, equipment must be thoroughly rinsed to prevent discoloration of a patient’s skin or mucous membrane.

2.5 Peracetic Acid

Peracetic, or peroxyacetic, acid is characterized by a very rapid action against all microorganisms. A special advantage of peracetic acid is it has no harmful decomposition products (i.e., acetic acid, water, oxygen, hydrogen peroxide) and leaves no residue. It remains effective in the presence of organic matter and is sporicidal even at low temperatures. Peracetic acid can corrode copper, brass, bronze, plain steel, and galvanized iron but these effects can be reduced by additives and pH modifications. It is considered unstable, particularly when diluted; for example, a 1% solution loses half its strength through hydrolysis in 6 days, whereas 40% peracetic acid loses 1 to 2% of its active ingredients per

month. It is used in automated machines to chemically sterilize medical, surgical, and dental instruments (e.g., endoscopes, arthroscopes).

2.6 Peracetic Acid and Hydrogen Peroxide

Two chemical sterilants are available that contain peracetic acid plus hydrogen peroxide (0.08 peracetic acid plus 1.0% hydrogen peroxide [no longer marketed], 0.23% peracetic acid plus 7.35% hydrogen peroxide). The bactericidal properties of peracetic acid and hydrogen peroxide have been established. Manufacturer's findings demonstrated that this product inactivated all microorganisms with the exception of bacterial spores within 20 minutes. The combination of peracetic acid and hydrogen peroxide has been used for disinfecting hemodialyzers.

3.0 APPENDICES

Appendix 1 – Classes of Organizms Ranked in Order of Susceptibility to Disinfectants

Bacteria with Spores (B. subtiles, C. tetani, C. difficile, C. botulinum)
Protozoa with Cysts (Giardia lablia, Cryptosporidium parvum)

Mycobacteria (M. tuberculosis, M. avium-intracellulare, M. chelonae)

Non-Enveloped Viruses (Coxsachievirus, poliovirus, rhinovirus, Norwalk-like Virus, hepatitis A virus)

Fungi (Candida species, Cryptococcus species, Aspergillus species, Dermatophytes)

Vegetative Bacteria (Staphylococcus aureus, Salmonella typhi, Pseudomonas aeruginosa, coliforms)

Enveloped Viruses (Herpes simplex, varicella-zoster virus, cytomegalovirus, measles virus, mumps virus, rubella virus, influenza virus, influenza virus, respiratory syncytial virus, hepatitis B & C viruses, hantavirus and human immunodeficiency virus)

Appendix 2 – Selection and Use of Disinfectants

Disinfectant	Uses	Advantages	Disadvantages
Alcohols ▪ **See Ethyl Alcohol MSDS on page 13** ▪ **See Isopropyl Alcohol MSDS on page 20**	Intermediate level disinfectant. Disinfect thermometers, external surfaces of some equipment (e.g., stethoscopes). Equipment used for home health care. Used as a skin antiseptic.	Fast acting. No residue. Non staining.	Volatile. Evaporation may diminish concentration. May harden rubber or cause deterioration of glues. Intoxicating.
Chlorine ▪ **See MSDS on page 27**	Intermediate level disinfectant. Disinfect hydrotherapy tanks, dialysis equipment, cardiopulmonary training manikins, environmental surfaces. Effective disinfectant following blood spills; aqueous solutions (5,000 ppm /1:10 bleach) used to decontaminate area after blood has been removed; sodium dichloroisocyanurate powder sprinkled directly on blood spills for decontamination and subsequent cleanup. Equipment used for home health care. Undiluted bleach can be used as a high level disinfectant.	Low cost. Fast acting. Readily available in non-hospital settings.	Corrosive to metals. Inactivated by organic material. Irritant to skin and mucous membranes. Use in well-ventilated areas. Shelf life shortens when diluted (1:9 parts water)

Formaldehyde ▪ **See MSDS on page 36**	Very limited use as chemisterilant. Sometimes used to reprocess hemodialyzers. Gaseous form used to decontaminate laboratory safety cabinets.	Active in presence of organic materials.	Carcinogenic. Toxic. Strong irritant. Pungent odor.
Ortho-phthalaldehyde (OPA-0.55% solution) ▪ **See MSDS on page 44**	Superior mycobactericidal activity, acts within 5 minutes. When tested against a wide range of microorganisms, OPA showed good activity.	Shorter process time (12min); No activation. Not a known irritant to eyes and nasal passages. No vapor ceiling limit. Weak odor.	Stains protein gray; not 100% sporicidal; Higher cost.
Hydrogen peroxide gas plasma ▪ **MSDS Not Available**	45 min. cycle time. Clean room sterilization, broad spectrum sterilization.	Very effective sterilization process. Leaves no toxic residues.	Capital equipment cost. New technology - May be less effective for pathogens buried in a thin organic film; most suited for dry objects.
Ethylene oxide gas (ETO) ▪ **See MSDS on page 51**	Sterilization of large batches of temperature-sensitive hospital supplies; 30-50C, 2 to 8 hrs, 40-50% RH typical.	Used since the 1950s. Effective at penetrating small orifices/channels. Effective for viruses, bacteria and spores.	Capital equipment cost. Gas is extreme irritant and flammable. Gas must be vented before exposure to personnel.

Glutaraldehydes ▪ **See MSDS on page 57**	2% formulations — high level disinfection for heat sensitive equipment. Most commonly used for endoscopes, respiratory therapy equipment and anesthesia equipment.	Noncorrosive to metal. Active in presence of organic material. Compatible with lensed instruments. Sterilization may be accomplished in 6-10 hours.	Extremely irritating and toxic to skin and mucous membranes. Shelf life shortens when diluted (effective for 14-30 days depending on formulation). High cost. Monitor concentration in reusable solutions.
Hydrogen Peroxide liquid ▪ **See MSDS on page 64**	Low level disinfectant (3%). Equipment used for home health care. Cleans floors, walls and furnishings. High level disinfectant (6%). Effective for high level disinfection of flexible endoscopes. Foot care equipment. Disinfection of soft contact lenses. Higher concentrations used as chemisterilants in specially designed machines for decontamination of heat sensitive medical devices. Stabilized hydrogen peroxide (0.5%) is used a high level surface disinfectant.	Strong oxidant. Fast acting. Breaks down into water and oxygen.	Can be corrosive to aluminum, copper, brass or zinc. Surface active with limited ability to penetrate.

Sources:
Handwashing, Cleaning, Disinfection and Sterilization in Health Care. CCDR 24S8, December 1998: Health Canada, and W. Rutal and D. Weber, *New Disinfection and Sterilization Methods*, Emerging Infectious Diseases, Vol. 7, No. 2, Mar-April 2001, U.S. CDC.

Hydrogen Peroxide Grades

3% Hydrogen Peroxide (Drug/Grocery Store Variety)

Used as antimicrobial agent for treating wounds and sanitizing agent
[Made from 50% Super D Peroxide, Diluted. Contains stabilizers - phenol, acetanilide, sodium stannate, tetrasodium phosphate among them. Do not ingest.

6% Hydrogen Peroxide

Used by Beauticians for Coloring Hair. Used as sanitizing agent.
Comes in strengths labeled 10,20,40 volume. Must have activator added to be used as a bleach. Contains stabilizers, additives, and impurities dependent on manufacturing and dilution process. Do not ingest.

30% Reagent Hydrogen Peroxide

Used in medical research. Contains stabilizers, additives, and impurities dependent on manufacturing and dilution process. Do not ingest.

30-32% Electronic Grade Hydrogen Peroxide

Used for washing transistors and integrated chip parts before assembly. Contains stabilizers, additives, and impurities dependent on manufacturing and dilution process. Do not ingest.

35% Food Grade Hydrogen Peroxide (Also 50% Food Grade H2O2)

Also used to spray inside of foil lined containers for food storage - known as the aseptic packaging system. Contains stabilizers, additives, and impurities dependent on manufacturing and dilution process. This Food Grade Hydrogen Peroxide is Stabilized using tin based formulations.

35% Technical Grade Hydrogen Peroxide

Used for wastewater treatment and the disinfection of potable water, cosmetics, and laundry applications. [May contain a small amount of phosphorus to neutralize any chlorine in the water it is combined with.]

35% Standard Grade Hydrogen Peroxide (Also 50%, 60%, 70% Standard Grades)

Used mainly for bleaching in the pulp and paper industry and in the textile industry; oxidation reactions in the chemical industry; environmental processes (detoxification and deodorization). Used for wastewater treatment. Contains stabilizers, additives, and impurities. Do not ingest.

90% Hydrogen Peroxide

Used by the military as a source of oxygen for rocket propulsion.

Intentional Additives to Hydrogen Peroxide and Impurities	
Additives	**Purpose**
Tin (Stannate)	Stabilizes product against decomposition caused by heavy metals
Phosphate	Stabilizes product against decomposition caused by chlorine or heavy metals
Nitrate	Acts as an inhibitor against the corrosion of aluminum
Impurities	**Source**
Carbon	Organic contamination from the "working solution" or anthraquinone
Aluminum	From contact with metallic process equipment and piping
Chloride	From plant water supply
Sulfate	From plant water supply
Ammonium	From plant water supply or degradation of organic amines

TECHNICAL DATA SECTION

MATERIAL SAFETY DATA SHEETS