Disinfectants:

What's in Your Bucket?

Part II

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This is the second part of a four part series on disinfectants intended to educate and inform IEHA members and non-members alike. Part I can be found in the January, 2006 issue of EHT. With each of these four articles, there is a test of the reader's knowledge and grasp of these important concepts. You will have an opportunity to take the exam and submit it for continuing education units (CEU's) of credit toward maintaining your Certified Executive Housekeeper (CEH) or Registered Executive Housekeeper (REH) status.

The outline for this series is adapted with revisions from a reference book that should be on every IEHA member's bookshelf. The title is, "The Practical Application of Disinfection and Sterilization in Health Care Facilities" and is co-authored by James C. Cokendolfer and Jill F. Haukos. While this author does not agree with everything written in the guide by Cokendolfer and Haukos, this book has proven to be essential as a reference for questions surrounding the topic of chemical disinfectants and the process of disinfecting environmental surfaces.

In this second installment, we want to have a discussion of the methods used to register disinfectants with EPA; what to look for when reading a germicide label; OSHA's attempt to protect workers exposed to bloodborne pathogens; and, the scientific guidelines and other governmental standards.

Using best management practices for disinfecting will help insure that you are cleaning appropriately to kill the bugs-microbes-you need to kill. Because disinfectants are designed to kill, they are toxic. Chemicals used as disinfectants can be corrosive, irritants and possibly carcinogenic. With best management practices use only the amount of disinfectant necessary to do the job. Ultimately, best management practices protect patients, employees and the environment.

That being said, there is a myriad of federal government agencies that have the regulatory oversight of disinfectants, sterilants, and antiseptics and their use by workers.
Some of those agencies are:

- EPA (Environmental Protection Agency)
- FDA (Food and Drug Administration)
- FTC (Federal Trade Commission)
- OSHA (Occupational Health and Safety Administration)

EPA

When the EPA was formed in 1970, the use and dumping of pesticides was a big problem in America. The US Department of Agriculture held that responsibility until the formation of the EPA. Because disinfectants are designed to kill living organisms on inanimate objects, the EPA regulates them as "pesticides".

OPP

The Office of Pesticide Programs (OPP) and Office of Compliance Monitoring are responsible for evaluating pesticide registration, as well as planning and coordinating pesticide compliance and enforcement activities, respectively. The Antimicrobial Program Branch (APB) within the OPP is directly responsible for registering disinfectants and sterilants.

For clarification, there is a distinct difference between antimicrobials and disinfectants. Disinfectant = a chemical intended to destroy or inactivate microorganisms on inanimate surfaces. Antimicrobials = any agent that kills or inhibits the growth or replication of microorganisms; term encompasses both antiseptic and disinfectant products.

FIFRA

The Federal Insecticide, Fungicide, and Rodenticide Act (U.S. EPA, 1988) is a law administered by the EPA by regulating disinfectants as pesticides. A pesticide is defined as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest…" Disinfectants destroy or prevent "pests" (living microorganisms, pathogens, bacteria, etc.). Disinfectants are used to maintain the public's health and must be tested against a standard established by the EPA to verify efficacy.

~ Testing: Validation of Product Efficacy ~

The GAO (the General Accounting Office) determined in 1990 that the EPA did not know whether disinfectants and sterilants killed the germs as claimed on product labels for the following four reasons

- "The methods and performance standards used to assess the efficacy of disinfectants had been, and continues to be, the source of scientific controversy.
- The EPA had made little progress in resolving these controversies because of budget constraints and inadequate research management.
- The EPA lacked sufficient internal controls to ensure the quality and integrity of the data that registrants submitted on disinfectant efficacy.
- The EPA lacked an enforcement strategy to ensure that, once registered, disinfectants sold and distributed in the marketplace worked as claimed."1

At the time of these GAO findings, it was estimated that up to 20% of the "EPA registered disinfectants" were ineffective. The public's health was being compromised when the EPA was directed to reevaluate the efficacy testing of sterilants and other products. The GAO had these particular concerns:

1. Human exposure to antimicrobial chemicals may be more significant than once thought and that additional, long-term toxicology data may be necessary for these chemicals.
2. Unsupported labeling and advertising claims were made by some antimicrobial pesticide registrants, thus creating a false sense of security among health care professionals relying on the product.
3. Test methods used to evaluate the efficacy of antimicrobial products may be unreliable.2

AOAC Testing

The EPA announced in 1990 the initiation of a three-step program to validate the efficacy of all (1) chemical sterilants, as well as (2) tuberculocidal, and (3) hospital disinfectants. Chemical sterilants are used as cold sterilants on medical devices that cannot be steam sterilized.

Under the new EPA program a product was tested one or two batches using the Association of Official Analytical Chemists (AOAC) Sporicidal Test methodology. The Association of Official Analytical Chemists is a scientific organization devoted to the validation of methods of analysis; AOAC-approved methods are used to determine the antimicrobial activity of disinfectants and sterilants.

"If the product passed the screen, no further testing was required. However, if the product failed the AOAC screen, enforcement action was taken to prohibit further sale and distribution of the specific batch(es) tested, and further testing of more batches was conducted. If three or more batches failed, enforcement action was taken to prevent all commercial movement of all batches of the product. All sterilant products tested remained on the market while the EPA conducted the efficacy of testing." 3

Tuberculocidal

A tuberculocidal disinfectant is an intermediate-level disinfectant (refer to "Part I, Disinfectants-What's in Your Bucket". pg. 5, January 2006/Executive Housekeeping Today). The tuberculocidal claim is issued to those products with proven efficacy against Mycobacterium bovis or M. tuberculosis.

"Potency against Mycobacterium tuberculosis has been recognized as a substantial benchmark. However, the tuberculocidal claim is used only as a benchmark to measure germicidal potency. Tuberculosis is not transmitted via environmental surfaces but rather by the airborne route. Accordingly, use of such products on environmental

surfaces plays no role in preventing the spread of tuberculosis. However, because mycobacteria have among the highest intrinsic levels of resistance among the vegetative bacteria, viruses, and fungi, any germicide with a tuberculocidal claim on the label is considered capable of inactivating a broad spectrum of pathogens, including such less-resistant organisms as bloodborne pathogens (e.g., HBV, HCV, and HIV). It is this broad-spectrum capability, rather than the product's specific potency against mycobacteria, that is the basis for protocols and regulations dictating use of tuberculocidal chemicals for surface disinfection." 4

Hospital Disinfectant
Disinfectants with effectiveness against Salmonella cholerasuis, Staphylococcus aureus, and Pseudomonas aeruginosa can be labeled as "hospital disinfectant" or "hospital-level disinfectant".

"EPA requires manufacturers to test formulations by using accepted methods for microbicidal activity, stability, and toxicity to animals and humans. Manufacturers submit these data to EPA with proposed labeling. If EPA concludes a product may be used without causing unreasonable adverse effects, the product and its labeling are given an EPA registration number, and the manufacturer may then sell and distribute the product in the United States. FIFRA requires users of products to follow the labeling directions on each product explicitly. The following statement appears on all EPA-registered product labels under the Directions for Use heading: "It is a violation of federal law to use this product inconsistent with its labeling." This means that healthcare professionals must follow the safety precautions and use directions on the labeling of each registered product. Not following the specified dilution, contact time, method of application, or any other condition of use is considered misuse of the product."5

~ What to Look For When Reading a Germicide Label ~

Review the labels of your current disinfectants. Do these solutions match the profile of the microbes you need to kill? The labels of concentrated disinfectants also state the proper level of dilution for maximum effectiveness.

Product sales literature and labels must accurately communicate important precautions and instructions to the user so that each product is effective without causing unreasonable adverse effects to humans or the environment (US EPA, 1994). In addition, the label is a legal, enforceable document.

Therefore, labels must meet the following general criteria (US EPA, 1992):

- Be clear and understandable to the user under normal conditions.
- Provide accurate precautions and directions that protect the user, other humans, and the environment.
- Contain no false or misleading statements or implied federal government approval or endorsements.
- Clearly distinguish between what is mandatory and enforceable and what is only a recommendation and cannot be enforced.
- Comply with the EPA's regulatory requirements as listed below.

Ten specific items must appear on product labels (item numbers refer to corresponding numbers shown on a sample label in the figure);

Sample layout for an antimicrobial pesticide label (numbers refer to item numbers in the text below).

ITEM 1—Product Name, Brand, or Trademark. The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product cannot be false or misleading.

ITEM 2—Company Name and Address. The name and address of the producer or person for whom the product is produced are required on the label and should be located at the bottom of the front panel or at the end of the label text.

ITEM 3—EPA Registration Number. The registration number assigned by EPA to the antimicrobial product must appear on the label, preceded by the phrase "EPA Registration No." or "EPA Reg. No." The EPA Registration Number is composed of at least two sets of numbers divided by a hyphen. The first set of numbers (e.g., 12345) identifies the registrant of the product. The second set of numbers (e.g., 67) identifies the specific product. If there is a third set of numbers (e.g., 12345-67-8912), this indicates that the product is a supplemental registration; see "Supplemental Registration" below for more information.

ITEM 4—EPA Establishment Number. The EPA establishment number, preceded by the phrase "EPA Est.," is the establishment where the product was produced, and may appear anywhere on the label.

ITEM 5—Net Contents. A net contents statement is required on antimicrobial pesticides. The preferred location is on the lower front panel immediately above the company name and address, or at the end of the label text. Net contents must be expressed in conventional American units of ounces, pints, quarts or gallons for liquids or in pounds and ounces for dry formulation.

ITEM 6—Ingredients Statement. An ingredients statement is required on the label and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients, with a total of 100%. Inert

ingredients, although possibly hazardous to humans, are not required to be detailed on the label.

ITEM 7-12—Warning and Precautionary Statements. Precautionary statements are required on all labels. These statements inform you of the proper precautions to take to better protect yourself and others from harmful effects of pesticide exposure. Hazard statements are not located in the same place on all pesticide labels. Precautions include:

Item 7—Human Hazard Signal Words (Danger/Poison, Warning, Cautions). Human hazard signal words indicate the level of toxicity of the pesticide product. Further discussions of toxicity categories will be held in Part IV.

Item 8—Child Hazard Warning (Keep Out of the Reach of Children). The Child Hazard Warning must be on the front panel of the label on all pesticide products.

Item 9—Statement of Practical Treatment. Statements of Practical Treatment can include information on:

Signs and symptoms of poisoning
First aid
Antidotes (if appropriate)
Note to physicians in the event of poisoning

Item 10—Hazards to Humans and Domestic Animals. These statements provide information about routes of pesticide exposure to humans (i.e., mouth, skin, lungs) and specific actions to take to prevent pesticide exposure (e.g., protective clothing, respirators).

Item 11—Environmental Hazards. If a pesticide is markedly hazardous to wildlife, the label must bear special toxicity statements such as "this product is highly toxic to birds, or to fish". General environmental precautions may include "do not apply directly to water, or do not contaminate water, food, or feed by storage and disposal of the pesticide."

Item 12—Physical/Chemical Hazards. These statements provide information about the flammability or explosive characteristics of the pesticide product.

ITEM 13—Storage and Disposal. All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes and chemical content.

ITEM 14—Directions for Use. Directions for use must be stated in terms that are easily read and understood by the average person likely to use or to supervise the use of the product. When followed, directions must be adequate to protect the public from fraud and personal injury, as well as prevent unreasonable adverse

environmental effects (including medical instruments). Directions for use must include the following:

- The site(s) of appropriate application
- Identification of the target microorganisms that the product will be effective in controlling at each use site
- The dilution and rate of application to be used for each site and micro-organism
- The method of application, including instruction for dilution, if required, and type(s) of application apparatus or equipment required
- The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects to the environment
- Any limitations or restrictions on use required to prevent unreasonable adverse effects (i.e., requirements for ventilation, respirators, protective clothing, etc.) when using the product.

ITEM 15—Misuse Statement. All products must bear the misuse statement, "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling." That would include adding other chemicals (like a deodorizer) to the in-use product. Or, adding more chemical than the label requires just because a worker thinks the situation dictates they do so.

Collateral Labeling. Leaflets, data sheets, or other written, printed or graphic matter that is referred to on the label or accompanies the product are called collateral labeling. Such associated literature may not bear claims or representations that substantially differ from those accepted in connection with the registration of the product.

Supplemental Registration. The EPA allows a registrant of a pesticide product to distribute or sell its registered product under another company's name and address instead of, or in addition to, its own name. For example, ABC Company can manufacture a product called ABC Disinfectant (this would be an example of a "primary registration"). ABC can also sell that same chemical formulation to XYZ Company and XYZ can, in turn, rename it XYZ Disinfectant. ABC and XYZ Disinfectants are actually the same product, but with different names. The registration of the XYZ product would be termed a "supplemental registration" or a "distributor product." The distributor is considered an agent of the registrant and both the registrant and the distributor are accountable for violations pertaining to the distributor product.

It is important to note that supplemental registrations are only an extension of a currently registered pesticide product. They are a duplication of the primary registered product and must in turn, reflect any changes made to the basic registration as they occur. For example, both ABC and XYZ disinfectants should have the same active ingredients at the same percentages, same instructions, and same label claims. All legal action taken against the primary registered products (e.g., ABC

Disinfectant) will also affect supplementary registered products (e.g., XYZ Disinfectant).

The EPA Registration Number of a distributor product is the same as that of the primary registered product, but has, in addition, another hyphen followed by the "Distributor's" company number. For example, if the product is EPA Reg. No. 9999-8888, and the distributor's company number is 7777, then the distributor's number that would appear on the label would be EPA Reg. No. 9999-8888-7777.

~ What to Look for on a Label ~

The important points to find on an antimicrobial label are the following:

- EPA Registration Number—either as a set of two numbers (e.g., 9999-8888) or three numbers (e.g., 9999-8888-7777)
- Label instructions—clear and appropriate for your situation
- Use and reuse instructions—clear and specific (pre-clean?)
- Dilution instructions—clean and specific (what ppm water hardness, sterile broth, in the presence of blood, different pathogens, etc.)
- List of organisms the product will effectively control
- Contact times and temperatures

All this information should be clearly marked on the label and understandable to the reader. If it is not, I recommend that you look at other available chemical options. I also recommend communicating any problems or concerns to the product manufacturer. Manufacturers cannot begin addressing problems until they become aware of them.

Occupational Safety and Health Administration
"OSHA Instruction CPL 2-2.44C" "Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens Standard, 29 CFR 1910.1030" was issued by the federal agency on March 6, 1992. This document was written for OSHA's field inspectors who survey hospitals, dentist's offices, emergency response officials, schools, beauticians, tatooists, electrologists and day care centers. But, it provides those who clean facilities that might become contaminated with blood or other potentially infectious materials (OPIM) with cleaning instructions. Included in this document is new requirements on what disinfectants these groups needed to use to comply with OSHA; specifically, they now had to be prepared to appropriately disinfect any surface contaminated by human blood or OPIM.

OSHA's Bloodborne Pathogens Standard
OSHA is concerned about the health and safety of workers in America. With the emergence of HIV, HBV and AIDS in the '80's, OSHA developed its Occupational Exposure to Bloodborne Pathogens Standard, Final Rule in 1991 to protect employees from occupational exposure to bloodborne pathogens. The rule defines potentially

infectious materials as human blood, human blood components, products made from human blood, semen, vaginal secretions, cerebrospinal fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids. Housekeepers and those employed to clean and maintain the workplace are on the expansive list of those occupations with potential exposure to bloodborne pathogens. The Standard requires employers within all these occupations must have an Exposure Control Plan defining employee actions to avoid an exposure to any of these body fluids and steps to take in the event of an exposure. The Standard also states that employers must ensure that:

> "The worksite is maintained in a clean and sanitary condition…contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning." [6]

Bloodborne Pathogen Standard Compliance

Within this definition, the amount of blood required to cause "contamination" is defined as "any spill of blood." Therefore, a surface is just as contaminated with a speck of blood as it is with a pool of blood.

A strain of bacteria (*Mycobacterium tuberculosis or mTB)* causes tuberculosis (TB). Because of its hard "shell" members of *Mycobacterium* are resistant to chemical disinfectants. Both HIV and HBV are easily inactivated by lower-potency level disinfectants (Bond, 1994) such as quaternary ammonium compounds.

This is very important to understand. Cleaning blood of any amount with a product other than a tuberculocidal or a sodium hypochlorite (household bleach dilution of 1:10 for porous surfaces or 1:100 for nonporous surfaces) is not acceptable as being effective against *mTB*. Rubbing alcohols and hydrogen peroxide are not acceptable as being effective against mTB unless they are incorporated into a tuberculocidal disinfectant registered with the EPA.

<u>According to OSHA, quats are not acceptable for decontamination of blood or body fluid spills</u>. The following letter of interpretation was written to clarify the appropriate protocol for cleaning spills of an unknown bloodborne pathogen. The only situation where you might <u>*know*</u> for sure the bloodborne pathogen to be deactivated would be in a research lab setting where these viruses are present. If you don't know, you must use a product with an mTB claim for cleanup of blood spills.

April 1, 1997
Dear Mr. Bach:
This is in response to your letter of December 10, 1996. You have requested a clarification of the Occupational Safety and Health Administrations (OSHA) position on disinfectants claiming efficacy

against the Hepatitis B virus. You have asked if the products with the EPA approval meet the requirements of the Bloodborne Pathogens Standard without a registered tuberculocidal claim.
A review of the initial intent of the Bloodborne Pathogens Standard that specifically deals with the cleaning of contaminated work surfaces, i.e., 1910.1030(d)(4)(ii)(A), reveals that OSHA intended to provide a performance-based provision that would allow for future development of "appropriate disinfectant" products. OSHA has reviewed the information on the disinfectants and has reconsidered its position on EPA-registered disinfectants that are labeled as effective against HBV and HIV. OSHA's current stance is that EPA-registered disinfectants for HIV and HBV meet the requirement in the standard and are "appropriate" disinfectants to clean contaminated surfaces, **provided such surfaces have not become contaminated with agent(s) or volumes of or concentrations of agent(s) for which higher-level disinfection is recommended.** (Emphasis added)
It is important to emphasize the EPA-approved label section titled "SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 AND HBV Of SURFACES\OBJECTS SOILED WITH BLOOD\BODY FLUIDS." On the labels that OSHA has seen, these instructions require:

- personal protection devices for the worker performing the task;
- that all the blood must be cleaned thoroughly before applying the disinfectant;
- that the disposal of the infectious waste is in accordance with federal, state, or local regulations;
- that the surface is left wet with the disinfectant for 30 seconds for HIV-1 and 10 minutes for HBV.

OSHA would expect all such disinfectants to be used in accordance with their EPA-approved label instructions.

We thank you for your interest in workplace safety and health.

Sincerely,

John B. Miles, Jr., Director [Directorate of Enforcement Programs]
[Corrected 2/10/2005]

In closing, we have noted there are several agencies with regulatory jurisdiction and other groups proposing guidelines for the use of disinfectants. As a housekeeping or facility professional, you need to determine the appropriate steps to follow when establishing policies and procedures for cleaning of spills containing blood or other potentially infectious body fluids. Be aware that there may be laws put forth by local or state governments that may be more restrictive than the federal laws. Local and state laws cannot be less stringent, but may be more stringent.

Do not look to state or federal agencies with jurisdictional oversight to provide any assistance with choosing an appropriate disinfectant. They can simply provide you with an “all or nothing list”. These governmental agencies pass or fail a product based on a review of research test data.

A chemical’s submission has been reviewed and cleared marketing in the U.S. A product registered with the EPA is not promoted over any other product registered for the same task (i.e., hospital disinfectant, sterilants, etc.)

When writing your department or facility bloodborne pathogen exposure control plan, I recommend that you take a "big picture" approach. That is, don't target HIV or HBV as though those are the only bloodborne pathogens of concern. Look at all types of pathogenic microorganisms. The goal is to devise a plan that protects workers, patients and others from pathogens that could, realistically, be transferred from either direct or indirect contact with environmental surfaces. Work with your infection control department and this Association to devise a complete, workable plan.

In Part III, we will be looking at the standards and guidelines of the Centers for Disease Control (CDC), the Joint Commission for Accreditation of Healthcare Organizations (JCAHO), and the Association for Professionals in Infection Control (APIC). Additionally, we will look at the pros and cons of disinfectants such as bleach, peroxy compounds, alcohols, halogens, phenolics, quaternary ammonium compounds (quats) and new, emerging disinfectant products. Then, we will look into how to control selected microorganisms such as C-diff, CJD, HIV, HBV and *mTB*.

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[2] **The Practical Application of Disinfection and Sterilization in Health Care Facilities,** James C. Cokendolpher and Jill F. Haukos, The American Society for Healthcare Environmental Services and The American Society for Healthcare Central Services Professionals of the American Hospital Association, 1996; page 17

[3] **The Practical Application of Disinfection and Sterilization in Health Care Facilities,** James C. Cokendolpher and Jill F. Haukos, The American Society for Healthcare Environmental Services and The American Society for Healthcare Central Services Professionals of the American Hospital Association, 1996; page 17, 18

[4] **CDC MMJR**, Dec. 19, 2003/52 (RR 17); 62-64, Appendix A, Regulatory Framework for Disinfectants and Sterilants.

[5] **CDC MMJR**, Dec. 19, 2003/52 (RR 17); 62-64, Appendix A, Regulatory Framework for Disinfectants and Sterilants.

[6] **The Practical Application of Disinfection and Sterilization in Health Care Facilities,** James C. Cokendolpher and Jill F. Haukos, The American Society for Healthcare Environmental Services and The American Society for Healthcare Central Services Professionals of the American Hospital Association, 1996; page 29

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DISINFECTANTS -

WHAT'S IN YOUR BUCKET?

PART II

Quiz for CEU credit

1. [T or F] The EPA tests and approves disinfectants and sterilants.
2. The _____-approved methods are used to determine the antimicrobial activity of disinfectants and sterilants.
3. Leaflets, data sheets, or other written, printed or graphic matter that is referred to on the label or accompanies the product are called _____ _____.
4. _____ is the federal agency concerned with the health and safety of workers in America.
5. Disinfectants destroy or prevent the growth of or reduce the population of _____ on inanimate surfaces.
6. Disinfectants with effectiveness against *Salmonella cholerasuis*, *Staphylococcus aureus* and Pseudomonas *aeruginosa* can be labeled as _____ _____.
7. Tuberculosis is not transmitted via _____ _____ but rather by the airborne route.
8. The EPA registration number on a disinfectant label is composed of two sets of numbers divided by a hyphen. The first set of numbers (e.g., 12345) identifies the _____ of the product. The second set of numbers (e.g., 67) identifies the _____ _____. If there is a third set of numbers (e.g., 12345-67-8912), this indicates that the product is a _____ _____.
9. Give one example of what would constitute a violation of a disinfectant label (i.e., Misuse Statement, "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling".) _____ _____
10. T or F OSHA's Bloodborne Pathogen standard allows for disinfectants with a HIV/HBV claim to be used for cleaning/disinfecting blood spills.

Disinfectants - What's in Your Bucket?

Part II: Quiz Answers

1. F
2. AOAC
3. Collateral labeling
4. OSHA
5. Pests (living microorganisms, pathogens, bacteria)
6. hospital disinfectant or hospital-level disinfectant
7. environmental surfaces
8. registrant, specific product, supplemental registration
9. adding a deodorizer product or using more chemical than the label requires
10. F