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Learning Objectives

1. Discuss the regulatory bodies involved with disinfection in healthcare environments
2. Explain the various classes, types and applications of disinfectant chemicals used in these environments
3. Explain the important elements and information found on chemistry labeling

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Labels – They’re not just window dressing

by Myrna Kauffman, RN, CNOR

Every day, personnel in healthcare facilities work with cleaning chemistries to clean environmental surfaces, medical and surgical instruments, and patient use devices and equipment. The cleaning chemistries used in these facilities are different from the cleaning chemistries that we use in our homes, for good reason. They must be proven disinfectants with the capability to eliminate the types and levels of potential contamination found in healthcare centers. Often, this means that they are more concentrated and caustic than household cleaners, and require regulation and careful handling. For this reason, and because human health depends on it, central service/processing and environmental services staffs must have a thorough knowledge of proper cleaning and disinfection processes and of the products used in those processes.

Disinfectant classifications

Environmental cleaners are germicidal products used to clean all surfaces (inside or outside of healthcare facilities) other than surgical instruments. These are generally divided into two groups; limited efficacy disinfectants and general disinfectants. The limited efficacy disinfectant category applies to the germicides that kill either gram-positive or gram-negative bacteria. This disinfectant category includes products generally found on supermarket shelves that would not be used in a healthcare facility. The general disinfectant category applies to a product that kills both gram-positive and gram-negative bacteria.

Regulating healthcare chemistries

The primary regulatory agencies that influence the use of germicidal chemistries in healthcare facilities are the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA). Each of these regu-

latory agencies has different responsibilities, although FDA and EPA work closely to regulate liquid chemical germicides.

OSHA is interested in the regulation and proper use of germicidal cleaners to protect healthcare employees. Their goal is to minimize the risk of work-related exposure to potentially hazardous chemicals and to protect patients and visitors from exposure to pathogenic microorganisms.

FDA is involved with germicides to assure proper and effective cleaning, disinfection and sterilization of reusable medical devices. FDA considers liquid chemical germicides used for this purpose to be medical devices that are subject to the same review, testing and diligence as any other medical device.

EPA is interested in the proper registration, labeling and manufacturing of germicides to ensure that the product's disinfection and/or sterilization claims are clear and validated through testing.

A hospital-grade disinfectant is considered to be the strongest disinfectant used in healthcare facilities on environmental surfaces. All hospital-grade disinfectants must be registered with EPA, which reviews all the test data, labeling and product formulation to make sure that the chemistry or formulation meets the minimum requirements and any additional claims the manufacturer has made. The hospital-grade disinfectants that have met the minimum requirement, which is the ability to kill *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa*, provide low-level disinfection. The hospital-grade disinfectants that have an additional tuberculocidal activity claim provide intermediate-level disinfection.

Instrument cleaning products, another type of chemistry found in all hospitals, are usually detergents or enzymatic formulations. They are designed to remove bioburden and soils of various types from the surfaces of surgical instruments and devices. These types of chemistries typically do not have germicidal claims.

STERIS Coverage® Spray TB Plus
Ready to Use Disinfectant Cleaner

Number: 1629-WK

Medical / Surgical / Dental Equipment Disinfectant Cleaner

Bactericidal • Fungicidal • Virucidal • Tuberculocidal****

For Professional Use

ACTIVE INGREDIENTS:
n-Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈) dimethyl benzyl ammonium chloride0.154%
n-Alkyl (60% C₁₄, 32% C₁₆) dimethyl ethylbenzyl ammonium chloride0.154%
Isopropanol21.000%
OTHER INGREDIENTS78.692%
TOTAL100.000%

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CAUTION**

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION: Harmful if inhaled or absorbed through skin. Causes moderate eye irritation. Avoid breathing vapors and contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

See side panel for additional precautionary statements.

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WORKPLACE LABEL FOR IN PLANT USE ONLY. NOT ADEQUATE TO BE USED AS SHIPPER LABEL.

FIRST AID	
If inhaled	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
If on skin or clothing	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes.
If in eyes	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-548-4873 for emergency medical treatment information.

Physical or Chemical Hazards Do not use or store near heat or open flame.

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Coverage Spray TB Plus effectively kills the following microorganisms at room temperature (69°F/20°C) with a 30 second contact time: Herpes Simplex II Virus (HSV 2) G Strain, Human Immunodeficiency Virus (HIV-1) associated with AIDS and Influenza Virus Strain A2/Hong Kong, and effectively kills the following microorganisms at room temperature (69°F/20°C) with a 3 minute contact time: *Mycobacterium bovis BCG (tuberculosis) (TB), Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442, Salmonella choleraesuis ATCC 10708, Trichophyton mentagrophytes ATCC 9533, Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Rhinovirus ATCC VR-296 and Polio 1 Virus ATCC VR-58.

Description: Use where control of the hazards of cross-contamination is of concern. Coverage Spray TB Plus is particularly effective in: medical facilities, hospitals, surgical centers, isolation units, neonatal intensive care units, EMS/paramedic units, plasma pheresis centers, laboratories, dental offices, operating rooms, emergency rooms, morgues and other areas where the control of cross contamination is important. When used as directed, this product effectively cleans and disinfects hard non-porous environmental surfaces such as: medical equipment surfaces/devices, ophthalmic equipment surfaces/devices, dental equipment surfaces/devices, anesthesia equipment surfaces, infant care equipment (bassinetts, incubators, warmers), laboratory equipment/surfaces, operating room lights/tables, oxygen hoods, physical therapy equipment (such as empty whirlpool tanks), and other hard non-porous environmental

STORAGE AND DISPOSAL
Do not contaminate food or feed by storage or disposal. **Storage:** Store in cool, well ventilated area. **Product Disposal:** Unused product may be discarded by pouring down the drain and flushing with water. **Container Disposal:** Triple rinse empty container, then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill, or incinerate; or if allowed by state and local authorities, dispose of by burning. If burned, stay out of smoke.

EPA Est. 1130-IL-1
EPA Reg. No. 70144-1-1043

Product Made in U.S.A.

surfaces including those made of plastic (such as: polycarbonate, polyvinyl chloride, polypropylene and polystyrene), vinyl, stainless steel, painted surfaces, Plexiglas® and glass.

HIV-1 Precautions: Coverage Spray TB Plus effectively inactivates HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids and in which the surfaces/objects can be associated with the potential for transmission of the human immunodeficiency virus Type-1 (HIV-1) associated with AIDS. **Special instructions for cleaning and decontamination against HIV-1 of surfaces/objects soiled with blood/body fluids:**

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces/objects before disinfection. **Contact Time:** While the HIV-1 virus is inactivated in 30 seconds, allow the surface to remain wet for 3 minutes prior to wiping.

Infectious Materials Disposal: Cleaning materials used that may contain blood/body fluids should be autoclaved and/or disposed of in accordance with local regulations for infectious materials disposal.

SURFACES: Cleaning: Prior to surface disinfection, clean surfaces by saturating surfaces with Coverage Spray TB Plus and allowing surfaces to remain wet for 30 seconds; then wipe clean using a fresh paper or cloth towel. Repeat, if necessary, until surfaces are visibly clean. Make sure surfaces are free of all gross filth and heavy soil. Discard paper towels or launder cloth towels before reusing.

General Disinfection: Re-apply Coverage Spray TB Plus by sponge, cloth or spray to pre-cleaned surfaces. Allow surface to remain wet for 3 minutes at room temperature (69°F/20°C); then wipe dry using a clean paper or cloth towel. Discard paper towels, or launder cloth towels before reusing.

This product is not to be used as a terminal sterilant or high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body; or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter sterile areas of the body.

Different purposes and applications

In addition to understanding the classes of chemicals, hospital staff must know how to use them. Hospital surfaces such as floors, walls, countertops, light fixtures, furniture and patient care-related equipment can and do serve as intermediate hosts to both pathogenic and opportunistic microorganisms. These surfaces are considered a possible source of healthcare-associated infections and must be decontaminated with an appropriate disinfecting chemistry. In addition, different areas of the healthcare facility require different levels of decontamination. For example, a lobby bench may require a lower level of disinfection than the floor of an infected patient's room or an operating room.

Since there is no one-type-fits-all chemistry for all applications in hospitals, there is a lot to know about the multitude of products in use. It is critical for environmental staff to understand the properties and appropriate uses and handling of all the chemistries and formulations being used in their healthcare center, for several important reasons. The first is to ensure the safety of the first people to come into contact with the chemicals – hospital personnel. Then, when they're being applied, it's to maintain the integrity of hospital surfaces and devices, while effectively disinfecting them. Ultimately, it's to assure the safety of the facility's patients.

Labels are a robust resource

The labels on healthcare cleaning and disinfection formulations are regulated by EPA. To comply with the EPA require-

ments, the label must be clear and readily understood. The statements on the label must be accurate without any false claims and they must distinguish between mandatory and recommended action. Because they are so carefully prepared and thoroughly reviewed, the labeling on an EPA-registered germicidal cleaner provides an enormous amount of valuable information for the user.

Below is a list of the important information that should be available to hospital staff on every EPA-regulated label:

EPA Registration Number

A number is assigned to a product when it is registered with EPA. If this number does not appear on the front of the product label, it means that the product is not registered with EPA. The registration number shows that EPA has reviewed the product data and has determined that the product can be used with minimal risk if the directions for use are followed.

Active Ingredients

An active ingredient is known or proven to be responsible for killing microorganisms. All active ingredients must be listed by their proper chemical name and the percentage that exists in the product.

Inert Ingredients

The inert ingredients do not have an active role in the killing of microorganisms and do not have to be listed on the label. Only the percentage of inert ingredients in the germicide must be listed. The inert ingredients are usually added to serve other purposes, such as assisting in dis-

solving the active ingredient or affecting how the product works.

Precautionary Statements:

The precautionary statement lists all the information regarding the hazardous nature of the germicidal chemistry or sterilant. Here you will also find the directions for use, proper disposal methods, first-aid instructions, and general information for storage.

The directions for use are specific as to the dilution rate, time and temperature for greatest efficacy, and the appropriate protective clothing, masks, goggles to wear to reduce the risk of injury. The proper storage conditions section explains what actions and environmental conditions will help maintain the product until it is used and instructs on appropriate disposal of the diluted chemistry, any unused portion and the empty container. The first aid recommendations will detail proper action if someone has accidentally swallowed or had the chemistry splash on their skin or into their eyes. It may even have a "note to physicians" that will provide doctors with specific medical information.

Efficacy

The efficacy statement must list the specific microorganisms that the product was successfully tested against. If the product was tested under adverse conditions, e.g.: hard water and/or 5% serum, this information may also appear on the label. This is good to know, especially if your facility has hard water or performs a lot of orthopedic surgeries, for example.

See **SELF-STUDY** on page 32

Self-Test Answers: 1. A, 2. E, 3. B, 4. C, 5. A, 6. D, 7. B, 8. B, 9. E, 10. B.

SELF-STUDY SERIES

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SELF-STUDY from page 31

Warranty Statement

The warranty statement is intended to limit a company's liability or as a warranty for the product. The label will often have the manufacturer's name, address and telephone number in case of any questions that might arise during the use of the product.

Know thy chemistry

Staff can learn a great deal about EPA-registered chemistries by reading their labels and following all directions for use. In fact, there are important benefits to being a chemistry know-it-all.

For example, proper use of label-recommended PPE and handling will protect everyone who must handle the chemistry while it is in the facility. Following label directions on proper dilution, application and exposure time on surfaces will yield the assurance that you have safely and effectively removed microorganisms and other soils, and thereby protected patients and reduced the risk of cross-contamination. Following label instructions for proper storage will protect your supply-chain investment and optimize the useful life of these hospital-grade formulated products.

The more you know and understand, the more effective you will be at using these products and the better the results can be for your facility. **HPN**

References

1. Environmental Protection Agency (EPA), Pesticides: Regulating Pesticides; *Label Review Manual*, 2008 (NOTE: most of the chapters were updated in 2008, however some of the chapters have other dates listed...anywhere from 2003-2008).

2. Food and Drug Administration (FDA), *FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices*; March 2009.

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Labels – They're not just window dressing

Circle the one correct answer:

- To achieve a **low level disinfection** claim, a manufacturer must show the chemistry's ability to kill *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa*.
 - True
 - False
- To achieve an **intermediate level disinfection** claim, a manufacturer must show that the chemistry has the ability to:
 - Kill *Staphylococcus aureus*
 - Kill *Salmonella choleraesuis*
 - Be tuberculocidal
 - Kill *Pseudomonas aeruginosa*
 - All of the above
- The same cleaning chemistries can be used in all areas of the hospital.
 - True
 - False
- A registered chemistry must have a number from which of the following government agencies?
 - FDA
 - OSHA
 - EPA
 - None of the above
- Statements made on a label must distinguish between recommended and mandatory actions.
 - True
 - False
- All of the following in a disinfection cleaning chemistry must be listed on the label:
 - Active ingredients by name
 - Inert ingredients by name
 - Percentage of inert ingredients
 - A and C
- Which of the following government agency/agencies is concerned with the healthcare workers safety when using disinfecting chemistries?
 - FDA
 - OSHA
 - EPA
 - None of the above
 - All of the above
- The enzyme instrument cleaning chemistries that are used to clean surgical instruments and devices usually have germicidal claims.
 - True
 - False
- Information found with the Precautionary Statements includes:
 - The directions for use
 - Exposure time needed
 - Dilution rate
 - The temperature required to achieve maximum efficacy
 - All of the above
 - None of the above
- The limited efficacy disinfectants kill both gram-positive and gram-negative bacteria.
 - True
 - False

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