

## Chemicals Used in Central Sterile: Just How Safe Are They?

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### Objectives:

**Explain the differences between how the FDA and EPA classify germicides.**

**Discuss the process of how liquid chemical germicides are approved.**

**Discuss the Spaulding Classifications.**

Have you ever wondered just how those chemicals that you use for cleaning instruments and other equipment came into being? Every chemical that we use within the healthcare setting has had to go through a rigorous testing. When a manufacturer recommends a product for use with their equipment, they are basing their recommendation on several things. First and foremost is the degree of microbial killing

the chemical supplies. This is followed by what the composition and nature of the surface, item or device that needs to be treated. The final thing is the cost, safety and ease of use of the available product.

In the United States, liquid chemical germicides (disinfectants) are regulated by the EPA and the FDA. In healthcare settings, the EPA regulates disinfectants that are used on environmental surfaces or clinical contact surfaces, i.e., light handles, x-ray heads, drawer knobs or table surfaces and floors, walls or sinks in patient rooms. The Antimicrobial

Division, Office of Pesticide Programs of the EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide (FIFRA) Act of 1947 regulates the use of healthcare disinfectants. Under the FIFRA, any substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, including microorganisms but excluding those in or on living man or animals, must be registered before sale or distribution.<sup>1</sup> This incidentally is why the Office of Pesticide Programs of the EPA, takes care of disinfectants used by healthcare facilities.

The EPA requires all manufacturers to test their formulas by using current methods for defining microbial activity, stability and toxicity to animals and humans. This data is then submitted by the manufacturers to the EPA with the idea of how the labeling should look. If the EPA decides that the product can be used without any unreasonable adverse effects, the product and its labeling are given an EPA registration number, after which the manufacturer can sell and distribute to its hearts content. However, this does not mean you, as the user has no responsibility. Just as in everything else, you, as the user are required to use the product as the directions on the label state. This means that you need to use the product in the specified dilution, contact time, method of application or any other conditions that the label so directs. Also, since 1990, the EPA has implemented a post-regulation Antimicrobial

Product Testing Program that evaluates the potency and effectiveness based upon the product label claims.

The FDA regulates liquid chemical sterilants/high-level disinfectants, e.g., glutaraldehyde, hydrogen peroxide or paracetic acid that are used on critical and semicritical patient care devices. The FDA, under the authority of the 1976 Medical Devices Amendment to the Food, Drug and Cosmetic Act, regulates chemical germicides if they are advertised and marketed for use on specific medical devices, e.g., endoscopes, flexible. Interestingly enough, if a liquid chemical germicide is marketed for a specific device, this liquid germicide is also considered a medical device for regulatory purposes. Also, the manufacturer of a specific device or instrument is obligated under FDA regulatory authority to provide the user of the device the specific instructions on the safe and effective use of that device/instrument. This also must include the methods required to clean, disinfect and/or sterilize the item if it is to be marketed as a reusable medical device.

One of our bones of contention deals with how EPA and FDA classify disinfectants. The FDA adopted the same basic terminology and classification scheme as the CDC to categorize medical devices. These classifications are called the Spaulding Classifications. Also included in this terminology is the definition of antimicrobial potency for processing surfaces, i.e., sterilization and high, intermediate and low-level disinfection.

The EPA registers environmental surface disinfectants based on the manufacturer's microbiological activity claims when registering the disinfectants.

This difference has led to confusion on the part of users because the EPA does not use the same terms the FDA does, i.e., intermediate and low level disinfectants as are also used in the CDC guidelines. When deciding which chemical disinfectant to use when working in CS be aware that based on the Spaulding Classifications, what the item is being used for and what part of the body it encroaches denotes which disinfectant to use. For example:

- ◆ If the item to be used enters sterile cavities (knee joint) or the vascular system, the equipment used should be sterile. These items are considered critical by nature and are to be sterile.
- ◆ Items that come in contact with non-intact skin or mucous membranes are considered semi-critical and should receive minimally high-level disinfection before use. As a general rule, these items can also be sterilized as mucous membranes can also be susceptible to some organisms.
- ◆ Those items that only come in contact with intact skin are considered to be noncritical and receive intermediate level or low level disinfection or cleaning. Because intact skin is considered to be an effective barrier to almost any microorganism, most experts do not believe that anything higher than low level disinfection is necessary.

It is important for the CS member to remember that if disinfectants will kill microorganisms, they can also be harmful to the cells of the human body.

CS personnel must take precautions to avoid direct contact with these chemicals. PPEs should always be available to the CS member as should Material Safety Data Sheets (MSDS). These sheets will include information about the chemical disinfectant, its toxicity, its flammability, what the signs and symptoms of exposure are, whether or not it can be vaporized, etc. There is also information about how to dispose of the liquid chemical disinfectant as well as how to clean up a spill. Any disposal of chemical germicides should follow federal, state and local regulations. It is also important that any training be documented within the staff members' file in order to be compliant with many governmental agencies.

**POST-TEST**

**Chemicals Used in Central Sterile:  
Just How Safe Are They?**

1. In the United States, liquid chemical germicides (disinfectants) are regulated by the EPA and the FDA.

TRUE FALSE

2. The EPA requires all manufacturers to test their formulas by using 1950s methods for defining microbial activity.

TRUE FALSE

3. The FIFRA of 1947 regulates the use of healthcare disinfectants.

TRUE FALSE

4. If there is an EPA registration number on the liquid chemical germicide, you as the user have no responsibility for its use.

TRUE FALSE

5. Spaulding Classifications are divided into small, medium and large.

TRUE FALSE

6. Critical means that the item or equipment needs to be sterile before being used.

TRUE FALSE

7. The FDA regulates chemical germicides if they are advertised and marketed for specific medical devices.

TRUE FALSE

8. Non-critical items are items that only come in contact with intact skin.

TRUE FALSE

9. MSDS include information about liquid chemical germicides such as its toxicity.

TRUE FALSE

10. Any disposal of chemical germicides should follow hospital policies.

TRUE FALSE



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**0=Not Applicable, 1=Poor, 4=Excellent**

Author’s Knowledge of the Subject **0 1 2 3 4**

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**A CHRISTMAS PRAYER**

Loving father, help us to remember the birth of Jesus, that we may share in the song of the angels, the gladness of the shepherds, and worship of the wise men.

Close the door of hate and open the door of love all over the world. Let kindness come with every gift and good desires with every greeting. Deliver us from evil by the blessing which Christ brings, and teach us to be merry with clear hearts.

May the Christmas morning make us happy to be thy children, and Christmas evening bring us to our beds with grateful thoughts , forgiving and forgiven, for Jesus sake. Amen

Written by: Robert Louis Stevenson

