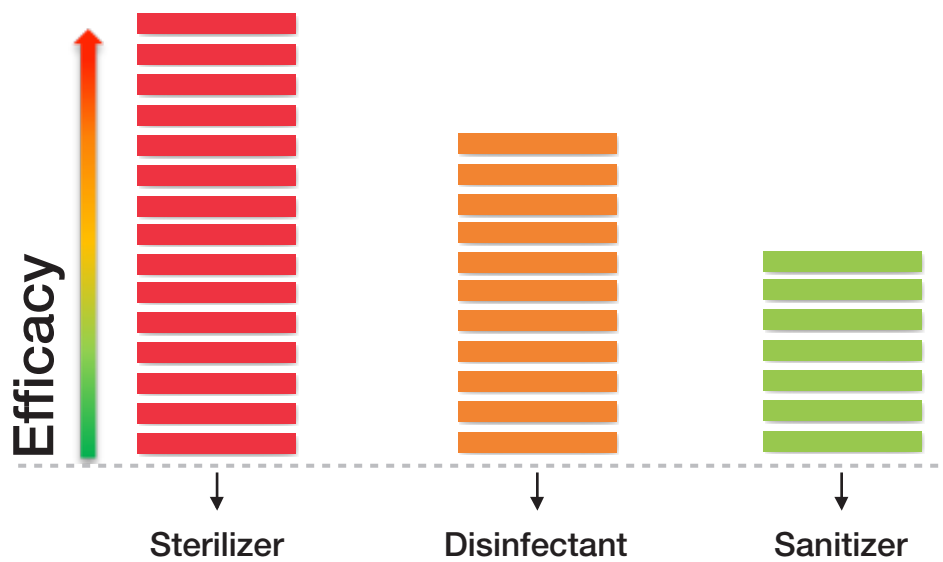


Antimicrobial Classes and Claims

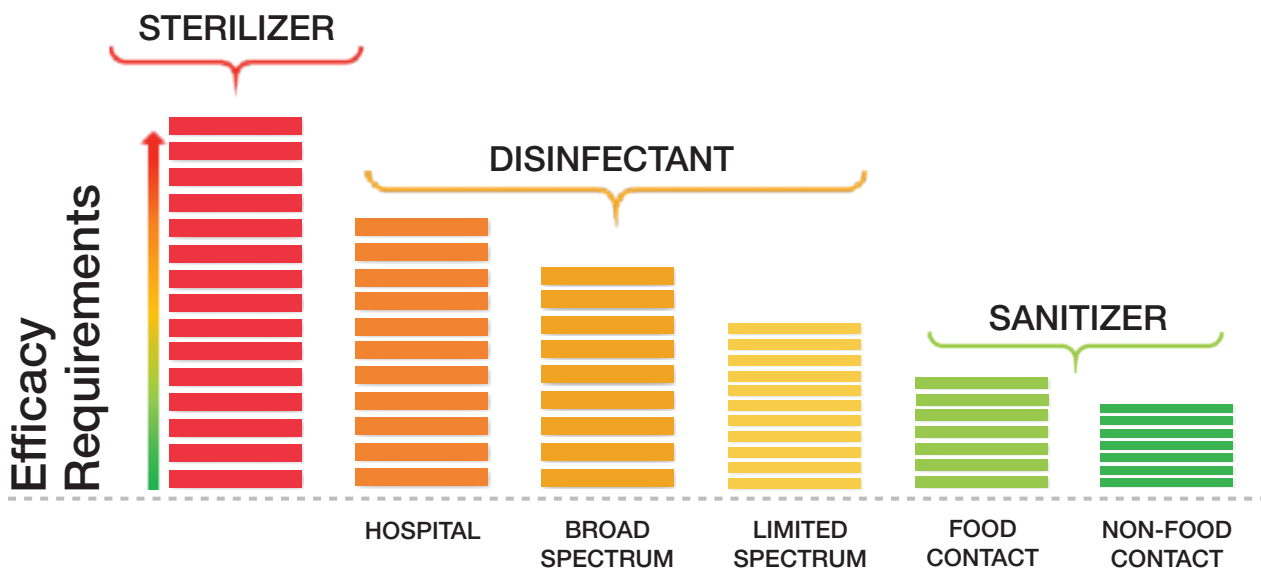
Claims around the efficacy of the product and its classification, such as sanitizer and or disinfectant, are driven by specific EPA approved testing criteria and efficacy against specific 'marker' organisms.

There are three general classes of antimicrobial pesticides:



- **Sterilizer:** used to destroy spores and all forms of microorganisms.
- **Disinfectant:** used to destroy or irreversibly inactivate microorganisms.
- **Sanitizer:** used to reduce, but not necessarily eliminate bacteria on inanimate surfaces by 99.9% or 99.999% (5-log).

These three general classes are broken down even further to more appropriately represent the different levels of disinfection and sanitization.



There are three different levels of Disinfectant:

■ **Hospital Disinfectant:** for use on inanimate objects in hospitals, clinics, or any other medical-related facility.

- This claim must be supported by efficacy against 3 'marker organisms': *Salmonella enterica* (formerly *Salmonella Choleraesuis*), *Staphylococcus aureus*, and *Pseudomonas aeruginosa*.
- Examples of Hospital-grade disinfectants include: Diversey Oxivir Tb, Clorox Germicidal Bleach.
- Such 'hospital-grade' disinfectants are not commonly found or used outside of a healthcare environment.
- There are a limited number of Hospital-grade disinfectants available on the market with a sporicidal *Clostridium difficile* (C. diff) claim. For example: Clorox Germicidal Bleach and Ecolab's OxyCide Daily Disinfectant Cleaner.

■ **Broad Spectrum Disinfectant:** means effectiveness against Gram-positive and Gram-negative bacteria.

- This claim must be supported by efficacy testing against 2 'marker organisms': *Salmonella enterica* (formerly *Salmonella Choleraesuis*) and *Staphylococcus aureus*.
- An example of a common 'general disinfectant' is lysol Disinfectant Spray.

■ **Limited Spectrum Disinfectant:** means disinfection or germicidal activity against one specific microorganism group (either Gram-negative or Gram-positive)

- This claim must be supported by efficacy testing against 1 'marker organism': *Salmonella enterica* (formerly *Salmonella Choleraesuis*) OR *Staphylococcus aureus*.
- The commercial product is required to specify which microorganism group on the label.
- A common example of this type of product may include toilet bowl cleaners.

There are two different levels of Sanitization:

■ **Food Contact Surface Sanitizer:** 99.999% bacterial reduction (including *E. coli*) and does NOT require a potable water rinse after use.

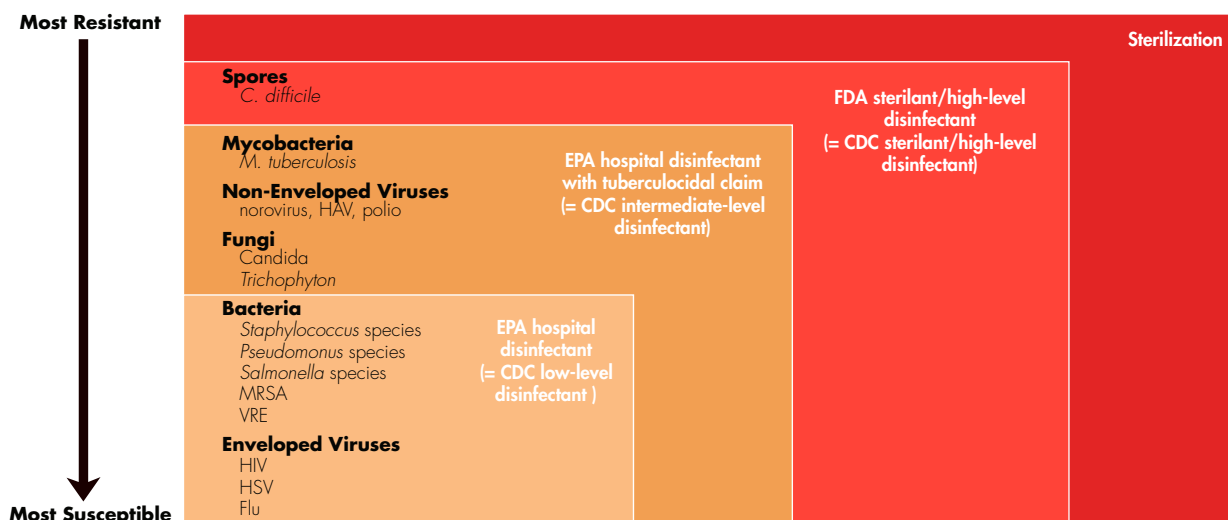
■ **Non-Food Contact Surface Sanitizer:** 99.9% bacterial reduction and DOES require a potable water rinse after use on food contact surfaces.

Additional Surface Cleaning and Disinfecting: Terms and Definitions

- **Cleaners:** (Detergents) disperse and remove soil and organic material from surfaces (They do not kill germs.)
- **Surface Cleaning:** a form of decontamination that renders the environmental surface safe to handle or use by removing organic matter, salts, and visible soils, all of which interfere with microbial inactivation.
- **Combination products:** clean and sanitize or clean and disinfect.
- **One-step cleaner and sanitizer/disinfectant:** a one-step cleaner and sanitizer/disinfectant means you can clean and sanitize/disinfect in one operation. Regardless if a product is approved as a one-step cleaner and sanitizer/disinfectant, the EPA requires that all disinfectants carry the following label direction: "For heavily soiled areas, a pre-cleaning step is required."
- **Ready-To-Use (RTU):** Premixed liquids sold in spray or pour bottles that require no additional labor to prepare for use.
- **Dilution:** The process of reducing the concentration of a solute in solution, usually by mixing with water. Products can be diluted manually by on-site staff, or with the assistance of a Dilution System.
- **Sporicide:** is an agent used to destroy bacterial spores.
- **Deodorizer:** is an agent used to absorb or eliminate offensive odors.
- **Fungicide:** is an agent used to kill or inhibit fungi or fungal spores.
- **Virucide:** is an agent that deactivates or destroys viruses.

Disinfection Hierarchy

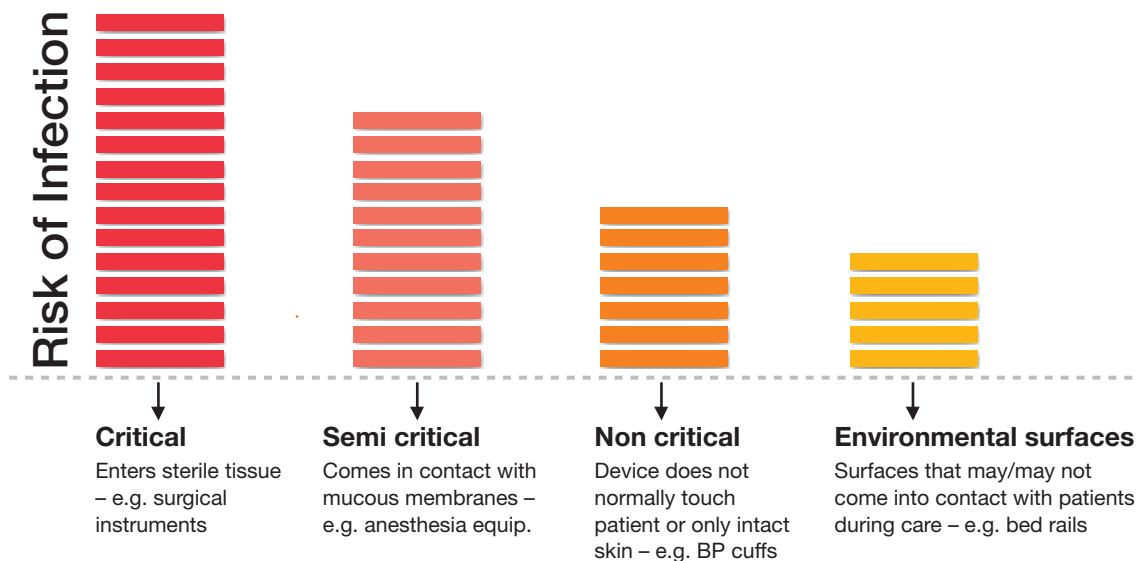
Organism vs. Processing/Disinfection Level Required



Source: Adapted from Bond WW, Ott BJ, Franke K, McCracken JE. Effective use of liquid chemical germicides on medical devices; instrument design problems. In: Block SS, ed. Disinfection, sterilization and preservation. 4th ed. Philadelphia, PA: Lea & Gebiger, 1991:1100. Rutala WA, Weber DJ, HICPAC. www.cdc.gov

Healthcare Spaulding Classification for Medical Devices and Levels of Disinfection

- The principles of cleaning and disinfecting environmental surfaces take into account the intended use of the surface or item.
- The classification system first proposed by Dr. E. H. Spaulding divides medical devices into categories based on the risk of infection involved with their use.
- This classification system is widely accepted and is used by the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), epidemiologists, microbiologists, and professional medical organizations to help determine the degree of disinfection or sterilization required for various medical devices.



- **Critical:** A device that enters normally sterile tissue or the vascular system or through which blood flows should be sterile.
 - Examples include surgical instruments and accessories, biopsy forceps, cardiac and urinary catheters, implants, needles.
 - Such devices should be sterilized.
- **Semicritical:** A device that comes into contact with intact mucous membranes and does not ordinarily penetrate sterile tissue.
 - Examples include respiratory therapy equipment, anesthesia equipment, flexible and laryngoscopes, bronchoscopes, GI endoscopes, cystoscopes.
 - These devices should receive at least high-level disinfection (sometimes sterilization).
- **Noncritical:** Devices that do not ordinarily touch the patient or touch only intact skin.
 - Examples include BP cuffs, stethoscopes, durable mobile patient equipment.
 - Can be decontaminated using EPA registered disinfectant.
- **Environmental Surfaces (added by CDC in 1991):** Surfaces within the patient environment that may or may not come into contact with patients during care.
 - Examples of surfaces and equipment that can reasonably be expected to be contaminated by bacteria (high touch surfaces) - bed rails, overbed tables, doorknobs, toilets, light switches, chairs, IV pumps, poles etc.
 - Can be decontaminated using EPA registered disinfectant.

