

# **Disinfectant Qualification & Comparative Effects of Terminal Sterilants, Disinfectants, Antiseptics, & Antibiotics**

AATB QA Workshop V  
New Orleans, Louisiana  
November 12 – 14, 2003



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American Association Of Tissue  
Banks

Quality Assurance Workshop 12 - 14  
November, 2003  
New Orleans, LA

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Disinfectant Qualification &  
Comparative Effects of Terminal  
Sterilants, Disinfectants,  
Antiseptics & Antibiotics

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The Microbial World



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## Definitions

- Chemical Germicide
- Disinfectant
- Sanitizer
- Sporicide
- Chemo Sterilizer
- Virucide
- Antibiotics
- Bioburden

EPA - reg effective w/ cleaning  
except for BMD (spes 7+10)

## Some Regulations

- Bone "As Human Tissue" - CBER, Section 361 of the Public Health Service and 21 CFR, part 1270.
- Bone as "Ingredient in Bone Repair Materials" - May be subject to FFDCA and 21 CFR, Part 820, 510K require generally.

## Proposed Rules

### Federal Register

- Display 1-5-01
- Publication 1-8-01
- FDA 21 CFR part 1271, 19 pages

"Current good tissue practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and enforcements."

Communicable  
 Bacterial  
 STD HIV  
 Flu  
 Whooping Cough  
 SARS  
 MERS  
 Influenza  
 Measles  
 Scarlatina  
 Meningococcal meningitis  
 B-strep  
 Hep B  
 Hep C  
 HIV  
 HBV  
 HCV  
 Polio  
 HAV  
 Staphylococcus aureus  
 E. coli  
 Salmonella  
 Shigella  
 Various Bacteria  
 and  
 fungi

**Qualification Aspects – 1**  
Requirements For Chemical Germicides

- Household Disinfectants
  - Staph aureus*
  - Salmonella*
- Hospital Disinfectants
  - Staph aureus*
  - Salmonella*
  - Pseudomonas aeruginosa*

Need drug Publ X  
 Pub/Sec Dep D10  
 Imp/A --- 4h  
 EGU-1 --- 7h AD  
 Vacc --- 8.5h  
 Polio E --- 13.5h

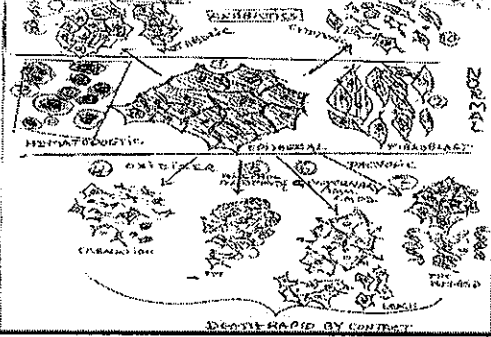
- Sporicide
    - Bacillus subtilis*
    - Clostridium sporogenes*
  - Additional Claims
    - TB
    - Viruses
    - Fungi
- Regulators: EPA  
Statute: FIFRA

**Qualification Aspects – II**  
Requirements For Healthcare Industrial Sites

- By Statute – None
- By GMP – US F. D. A.
- Statute – By Reference

Sites: Tissue, Pharmaceutical, Device,  
Cosmetics, Nutraceuticals, Biotechs etc

## The Effects of AntiMicrobials



*Handwritten notes:*  
 Cytokine  
 Bacteriophage  
 Spores  
 Chlorophyll  
 Photosynthesis  
 Lignin  
 Cellulose

## Failure of EPA-Registered Disinfectants Against Manufacturing & Plant Isolates "Wild Type"

AOAC Use-Dilution Test Disinfectants

- Bacteria – 20% Failure rate Pathogens & Non Pathogens (Gram negative rods)
- Fungi – 43% Failure rate
  - Penicillium
  - Cladosporium
  - Aspergillus

Oxidizers

- Bacteria – No Failures
- Fungi – No Failures

## Anti Microbial Agents

- Kill On Contact
  - Sporicides/Oxidizers
  - Disinfectants
  - Antiseptics
  - Certain Antibiotics (Poly Peptides)
    - G+ Bacitracin A
    - G+ Tyrothrycin
    - G- Polymyxin B

F=Fast S=Slow N=Narrow  
 B=Broad C=Contact M=Metabolism

DISINFECTANT	SPEED	SPECTRUM	PROTEIN
OXIDIZERS	++++	++++	INACTIVE
QUATS	+++	++	INACTIVE
PHENOLICS	++	++	NEUTRAL
ALDEHYDES	++	++++	INACTIVE
ALCOHOL	++	++	NEUTRAL

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D-Values  
 Chemical Germicides

Chemical	<i>B. Anthracis</i>	<i>B. Cereus</i>	<i>B. subtilis</i>
10% Bleach	4 min	4 min	5 min
3% H <sub>2</sub> O <sub>2</sub>	1 min	5 min	10 min
NaOH 0.5N	3 hrs	3 hrs	6 hrs
Citric Acid 1.5%	>6 hrs	>6 hrs	>6 hrs
EPA-Rg Quat. Disf	1.5 hrs	2.5 hrs	>6 hrs
Iodophor Antiseptic	10 min	15 min	15 min
Phenolic Antiseptic	>6 hrs	>6 hrs	>6 hrs
Aliphatic Antiseptic	3 hrs	>6 hrs	>6 hrs
70% Isopropanol	>6 hrs	>6 hrs	>6 hrs

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Inactivation Expressed as %  
 Viral Reduction  
 Vaccinia (Cowpox)

Germicide	5 sec.	10 min.
H <sub>2</sub> O <sub>2</sub> (3%)	90% (1-log)	100% >6 logs
EPA disinfectant	90% (1-log)	100% >6 logs
70% IPA	90% (1-log)	100% >6 logs
70% ETOH	<1 -log	100% >6 logs

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■ STEAM AUTOCLAVE

*B.stearothermophilus* - - - - - 1.5 min  
*B.pumilus, B.sphaericus* - - - - - < 1.0 min  
*B.subtilis, B.thuringiensis* - - - <1.0 min  
*B.cereus, B.anthraxis* - - - <1.0 min

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JMAD