

Who Regulates Antimicrobial Textiles, EPA, FDA or Nobody?

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Which of the following is the right answer?

- A. EPA
 - B. FDA
 - C. Nobody
 - D. It depends
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EPA: What are antimicrobial agents

- Substance or mixture of substances used to destroy or suppress the growth of harmful microorganisms on inanimate surfaces

--- Source: EPA website: “Antimicrobial Pesticide Products”



FDA: What are antimicrobial agents

- Antimicrobial agents are substances that kill or inhibit the growth of microorganisms.
- In certain instances when antimicrobial agents are included on a device, they will be considered **drugs** and the resulting device that includes the antimicrobial drug will be considered a **combination product** as defined in 21 CFR 3.2(e).

--Source: FDA Guidance on Medical Device Containing Antimicrobial Agents



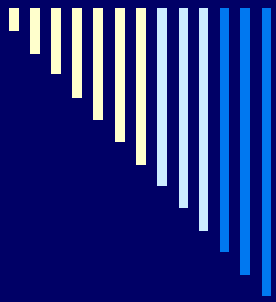
Easy Identification

- EPA regulates antimicrobial agents that control microorganisms as bacteria, viruses or algae on **nonliving surfaces**. (pesticides)
 - FDA regulates antimicrobial agents that control fungi, bacteria, virus or other microorganisms **in or on living humans or animals** (drugs)
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Is your antimicrobial textile product a medical device?

- FDA official definition: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
 - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
 - intended for use in the **diagnosis of disease** or other conditions, or in the **cure, mitigation, treatment, or prevention of disease**, in man or other animals, or
 - intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."



Not a device?



Antimicrobial textiles

EPA Classification

- Non-public health products – defined as products containing antimicrobials to control the growth of microorganisms that can cause spoilage or deterioration of products
 - Examples: odor control socks, tents treated with antimicrobial
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Antimicrobial textiles

EPA Classification

- Public Health Products – products containing antimicrobials to control microorganisms that are infections to humans in any inanimate environment.
 - Examples: antimicrobial hard surface wipes, etc
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Public Health Claims

- A claim for **control of specific microorganisms** or classes of microorganisms that are directly or indirectly infectious or pathogenic to man (or both man and animals).
 - A claim for the product as a sterilant, disinfectant, virucide or sanitizer, regardless of the site of use of the product, and regardless of whether specific microorganisms are identified.
 - A claim of **“antibacterial,” “bactericidal,” or “germicidal”** activity or references in any context to activity against germs or human pathogenic organisms implying public health related protection is made.
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Public Health Claims -ctd

- ❑ A claim for the product as a **fungicide against fungi infections or fungi pathogenic to man**, or the product does not clearly indicate it is intended for use against non-public health fungi.
- ❑ A claim to control the spread of allergens through the inhibition or removal of microorganisms such as mold or mildew.
- ❑ A non-specific claim that the product will beneficially impact or affect public health by pesticidal means at the site of use or in the environment in which applied.
- ❑ An unqualified claim of “antimicrobial” activity.

Source – EPA 2000-1



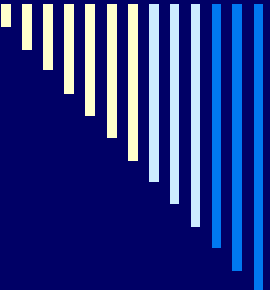
Non Health Related Claims

- A claim to **inhibit microorganisms** which may cause **spoilage or fouling** of the treated article or substance.
 - A claim to **inhibit offensive odors** in the treated article or substance.
 - EPA considers terms such as “antimicrobial,” “fungistatic,” “mildew-resistant,” and “preservative,” as being acceptable for **exempted treated articles** or substances provided that they are properly, and very clearly, qualified as to their intended non-public health use.
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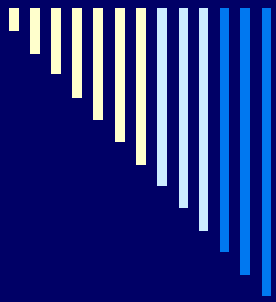
EPA Treated Item Exemption

- Known as the "Treated Articles Exemption," section 152.25(a) provides an exemption from all requirements of FIFRA for qualifying articles or substances treated with, or containing a pesticide, if:
 - (1) the incorporated pesticide is **registered for use** in or on the article or substance, and;
 - (2) the sole purpose of the treatment is to **protect the article or substance itself**.
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Want to make public health related claims?

- Register the antimicrobial treated item with EPA for specific claims with
 - Efficacy data
 - Safety data
 - Other applicable registration requirements
 - Federal registration and state registration
 - Example: antimicrobial hard surface wipe
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Yes it is a device,
so what?



Textiles as Medical Devices: FDA Device Classification

- Class I General Controls
 - Low risk
 - 510(K) exempted
 - Examples: bandage, shoe covers, mattress cover for medical uses
 - Class II General Controls and Special Controls
 - Medium risk
 - Examples: antimicrobial bandage
 - Class III General Controls and Premarket Approval
 - High risk
 - Examples: heart valves
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Premarket Notification 510K

- A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA. It is required for all medical devices that
 - if not exempted from 510(K)
 - Most Class II required (Most Class I exempted)
 - Adding antimicrobial usually requires 510(K)
 - if PMA is not required
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Elements of a 510(K) Application

- ❑ Cover letter
 - ❑ Table of contents
 - ❑ Statement of Intended Use
 - ❑ Truthful and accurate statement
 - ❑ Device description
 - ❑ Test data
 - ❑ Labeling
 - ❑ Substantial equivalence
 - ❑ Summary of Statement
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FDA requirements on Antimicrobials

- Identity of formulation
- Concentration
- Method of application to device
- Mechanism of action
- Antimicrobial activity spectrum
- Release of the antimicrobial agent
- Minimum effective concentration
- Toxicity

--Source: FDA Guidance



Identity of Chemical Formulation

- ❑ New antimicrobial? Existing antimicrobial?
 - ❑ EPA registration?
 - ❑ Has it been used in other medical devices that received FDA clearance/approval?
 - ❑ Concentration
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Method of Application

- Dipping/Padding
 - Spray
 - Coating
 - Mixed in raw material
 - etc
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Antimicrobial Supplier

- Quality system:
 - cGMP ?
 - ISO?
 - Patent/intellectual properties?
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Spectrum of Antimicrobial Activity

What are these problematic microbes?

- Antibacterial?
 - Antifungal?
 - Antimicrobial?
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Mechanism of Antimicrobial Action

- ❑ Slow acting? Quick acting?
 - ❑ Physically? Chemically?
 - ❑ Consumed? Permanent?
 - ❑ Durable? Non-durable? Semi-durable?
Rechargeable?
 - ❑ If leaching out, what is the MEC level?
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Biocompatibility/toxicity

- Cytotoxicity
 - ISO 10993 Part 5: Test for Cytotoxicity: in vitro Methods
 - Skin Irritation
 - Skin Sensitization
 - ISO 10993 Part 10 : Tests for Irritation and Delayed-Type Hypersensitivity
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Stability

□ Real Time Aging

- 25 C/60%
- 12 months, 24 months or 36 months

□ Accelerated Aging

- 40 C/75%
 - 3 months, 6 months or 9 months
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Antimicrobial Efficacy Study

- Test method
 - Qualitative?
 - Quantitative?
 - Start concentration
 - Contact time
 - Target microbes
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Antimicrobial Testing Lab

- GMP/GLP? ISO certified?
 - FDA registration?
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Most recent EPA enforcement actions

- ❑ **VF Outdoor**, Inc. and its North Face brand (\$207,000 for "antimicrobial" shoes)
- ❑ **Component Hardware Group, Inc.** (\$98,300 for "antimicrobial" Saniguard brand faucets, spigots, handles and similar hardware sold to medical institutions).
- ❑ **Home Depot** (\$230,000 for "antimicrobial" whirlpools and toilets)
- ❑ **Target Stores** (\$50,000 for "antimicrobial" mattress pads) and the parent of IO GEAR (\$208,000 for "antimicrobial" keyboards).



Recent FDA warning letter

- “For example in your website you state that XYZ utilizes a unique, highly effective solution called ABC, delivering a **fast kill rate across a broad spectrum of microbes** (data on file, available upon request).”
 - “immediately cease the dissemination of promotional materials for XYZ. Failure to promptly correct these violation(s) may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to **seizure, injunction and/or civil money penalties.**”
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Any Questions?

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