Antimicrobial Additives for the Healthcare Market: An Overview

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What is an Antimicrobial?

• Definition
  • ”Destroying or suppressing the growth of microorganisms” (Webster’s Dictionary)

• Utilized as additives in plastics used in the healthcare industry to destroy or suppress microorganism growth in order to minimize “biofilm” formation
How are Antimicrobials Different than Disinfectant Agents?

• Definition
  • “Disinfectants are antimicrobial agents that are applied to the surface of non-living objects to destroy microorganisms that are living on the objects”
  • Topical and not generally compounded into the polymer. Items in () are not generally used as topical disinfectants
    • Oxidizers
    • Alcohols
    • Aldehydes
    • Phenolics
    • Quaternary Ammonium Compounds
    • (Silver)
    • (Copper Alloys)
    • (Zinc)
  • Usually used in liquid form to kill microbes on a piece of equipment or area, e.g. hospital room
Healthcare Sites for Potential Microbe Growth

- Vascular Access/Fluid Management
- Tubing
- Airway Management
- Hospital Durables
- Device Housings
- Wound Care
Criteria for Antimicrobial Action

✓ Antimicrobial must work against the microorganism you are trying to kill or suppress:
  ▪ Bacteria, Fungi/mold, Algae or Virus
✓ Technology must be proven to work consistently as intended
✓ Technology must work in or on a variety of materials and surface types
✓ Technology must work in a variety of conditions and environments
Antimicrobials & Sterilization

**Antimicrobial**
- Utilized as additives in, or surface coatings on, medical plastics
- Destroy microorganism growth in order to prevent “biofilm” formation on device or surface substrates
- Two types of additives:
  - Organic
  - Inorganic

**Sterilization**
- Designed to kill microorganisms
- 3 main approaches for plastics:
  - Radiation: Gamma, E-Beam (increasing)
  - Ethylene Oxide (declining)
  - Steam Autoclave (Small % but increasing)
Microbial Attack on Any Plastic Product

- All are identifiable with EPA regulated uses except for **hygienic** effects:
  - Odor
  - Staining
  - Loss of electrical properties
  - Permeability
  - Loss of mechanical properties
  - Negative hygienic effects
  - Discoloration

- Supports pathogens
Two Types of Antimicrobial Effects

• Biocidal
  • Killing the organism
  • Inorganic additives only

• Biostatic
  • Preventing reproduction of the organism
  • Both organic and inorganic additives

Current market for antimicrobials is 2500+ tons of actual antimicrobial additive = $~200 – ~$275 million (US)

That 5+ million pounds of antimicrobial is estimated to be processed into about 60+ million pounds of formulated product
Two Types of Anti-microbial Needs

Customer

Type 1
Low Efficacy Threshold
- “Protect the Plastic”
  - Intuitive
  - Observable
  - Less Regulated
  - Mostly EPA

Type 2
High Efficacy Threshold
- “Kill Microorganism”
  - Quantifiable
  - Highly Regulated
  - Mostly FDA
Type 1 Customer – Low Efficacy Threshold

- Driving force – marketing advantage
  - Perception of safety & cleanliness
  - Product is protected
- Criteria for higher systems cost associated with antimicrobial
  - Higher sales of product
  - Higher price/margins
- Claim development – relatively simple
  - Cannot make any claims pertaining to a personal or public health benefit
  - “Protect or preserve the treated plastic article”
  - Medical device must still pass FDA 510K
  - EPA Regulated
Type 2 Customer – High Efficacy Threshold

• Driving force
  • Disease prevention caused by microorganism growth
• Criteria for higher systems cost associated with antimicrobial
  • Higher sales of product
  • Higher price/margins
  • Risk management
• Claims development – more complex
  • If the product makes claims pertaining to personal or public health benefit, then rigorous testing must be done to support the claim
  • FDA Regulated
Type 2 Customer – High Efficacy Threshold

- Type 2 Customers Address the Infection Control Market
  - Almost all Hospital Acquired Infections (HAI’s) are not caused by a patient’s original diagnosis
  - Most infections that become clinically evident 48 hours after admission or within 30 days after discharge from a hospital are considered HAI’s

- Minimizing Infection is Important
  - Hospitals are concerned with bacteria mostly, then fungi.
  - Contact Transmission is the most frequent mode of bacterial transmission.
  - New Medicare Regulations – Payments can be withheld for care associated with treating nosocomial infections resulting from certain catheter associated treatments
Antimicrobial Options for Medical Devices

- Surface coating
  - Works but has drawbacks
    - Surface treatment may get wiped off
    - Surface treatment may not be as long lasting

- Incorporating the antimicrobial into the polymer itself
  - Permanent
  - Melt blended in
  - Organic/inorganic additives possible
Types of Antimicrobials for Compounding into Plastics

1. Organic
   • Generally small molecules that are incompatible with the polymer matrix and diffuse to the surface of the polymer where they can interact with microorganisms

2. Inorganic
   • Mostly based on metal ions (such as silver). They are unreactive until released in association with another agent, such as moisture

   • Antimicrobial additives remain stored in the polymer being released gradually to the surface, providing longer lasting activity
Inorganic Antimicrobials

- Based on metal ions (such as silver). They are unreactive until released in association with another agent, such as moisture.
- Other metals, such as Zn, Cu, Se are also active if ionic.
  - Silver has the advantage of being less reactive with the environment.
- Biocidal and biostatic effect.
- Bound within a delivery system such as ceramic glass, doped titanium dioxides, zeolites.
- Density of metal ions and delivery system regulate how quickly ions are released and the duration of the action.
- Generally less sensitive to temperature than organic systems.
Silver as an Antimicrobial

- Silver metal, in itself, does not possess antimicrobial properties
- Silver ions, a by-product of oxidation, do have excellent antimicrobial properties
  - If silver ions are released too quickly, they may not be suitable for long term applications
  - If they are released too slowly, potency is limited
- Great for attacking bacteria. Also fungicidal effect

Ref.: www.thesilveredge.com
Organic Antimicrobials

- Generally small molecules that are incompatible with the polymer matrix and diffuse to the surface of the polymer where they interact with microorganisms
- Biostatic effect
- Reacts quickly to microorganism
- Diffuses out over time
- Sensitive to high processing temperatures
- Cost advantage
- Used in disposable products
Common Antimicrobial Technologies

- Thiabendazole
  - Organic
  - Effective against fungi
  - Film preservative
  - Can be transparent

- Isothiazolinone
  - Organic
  - Effective against some bacteria, fungi, some algae
  - Migratory

- Triclosan
  - Synthetic organic chemical
  - Many brands
  - Was commonly used in soaps, toothpaste, fibers, etc.
    - Taken out due to concerns on promoting resistance bacteria

- Triclosan Continued
  - Very potent
  - Concern is that bacteria will become more resistant over time
  - In general triclosan use is in decline
  - Not used a lot in Healthcare

- Zinc Pyrithione
  - Effective against fungi, bacteria
  - Used in cosmetics, paints, sealants
  - Migratory, supplied as a powder
Common Antimicrobial Structures

OBPA (10, 10-Oxybisphenoxarsine)

- Organometallic base
- Used in flexible PVC and polyurethane
- Effective against fungi
- Migratory
- Popular trade name is Vinyzene™
- Phased out in EU Jan. ‘13
- OK in US, → isothiazolinones

Note is Arsenic Containing, Concern is about Persistence
A Unique Approach by PolyOne

Antimicrobial polymer concentrates and compounds
US 20160235072 A1

ABSTRACT
Migratory assisting agents are used to improve antimicrobial efficacy of antimicrobial masterbatches, the polymer compounds these antimicrobial masterbatches are let down into, and the articles made therefrom. The migratory assisting agents function by carrying the antimicrobial agents while the migratory assisting agent transfers or “migrates” to the surface of a polymer compound or article formed from the polymer compound. As a result, antimicrobial agents are brought to the surface where there is exposure to bacterial contamination.

Problem to Be Solved: How to Utilize Existing Registered Antimicrobials more Effectively. Possible Solution: Utilize other Migratory Additives to Force Antimicrobials to the Surface
## Masterbatch Formulations: With and Without Migratory Additives

### Table 5: Masterbatch Formulations

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- **Antimicrobials**
  - Ionpure® WPA: Ag⁺
  - Intercide™ ZNP: Zinc Pyrithione
  - Pationic® 1052: Glycerol Monostearate, 60% mono
  - Chemstat® 1900: Proprietary fatty acid ester

- **Surface Active Agents**

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POLYONE CORPORATION

SPE ANTEC® Anaheim 2017 / 1752
### Final Formulations

#### Table 6: Compound Formulations and Antimicrobial Efficacy

<table>
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<tr>
<th>Compound Example</th>
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Ionpure® WPA: Ag⁺
Intercide™ ZNP: Zinc Pyrithione
Pationic® 1052: Glycerol Monostearate, 60% mono
Chemstat® 1900: Proprietary fatty acid ester
Migratory Additive Enhances Efficacy ~4-5 Orders of Magnitude

Table 6: Compound Formulations and Antimicrobial Efficacy

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Test Results

| Gram (-) log reduction # Escherichia coli | 0.16 | 1.23 | 0.00 | 2.00 | 5.20 | 5.20 | 4.80 | 5.00 | 4.80 | 4.80 | 5.20 | 5.20 |
| Gram (+) log reduction # Staphylococcus  | 3.92 | 0.58 | 1.28 | 2.93 | 5.20 | 5.20 | 3.90 | 4.00 | 3.90 | 3.90 | 4.20 | 4.20 |

Unfilled Arrows = No Mig. Add.
Filled = Mig. Add.
Red = PBT
Blue = PP
Ionpure® WPA, Intercide™ ZNP

2X level in 5, but same log kill
Efficacy Testing: Quantitative

• Used JIS Z1280 in this Patent Application.
• Method Uses a Bacterium Broth with Target Bacterium Level 2.5 to 10 x 10^5 Cells/ml
  • Test Sample with Antimicrobial and Control Placed in Petri Dish and Covered with Broth, Incubated for 24 Hrs.
  • Inoculum Washed Off Test Piece and Control
  • Viable Number of Bacteria Determined by Agar Culture
• Antibacterial Activity = R = U_t – A_t
  • Where U_t is the Average Log Number of Viable Bacteria after inoculation on Untreated Test Piece after 24 Hrs.
  • Where A_t is the Average Log Number of Viable Bacterial after Inoculation on Treated Test Piece after 24 Hrs.
  • For Example:
    • U_t = 10 x 10^5 cells/ml and A_t = 10 cells/ml
    • Then R = Log (10 x 10^5 cells/ml) – Log (10 cells/ml), which gives R = (6-1) = 5
    • Typically R is referred to as the “Log Kill” and in this case would be 5. “Log Kill” of 90% → “Log Kill of 1”, “Log Kill” of 99.9% → 3
Other Anti-microbial Tests

- USP 51 – antimicrobial effectiveness tests
- USP 1227 – Neutralization validation
- ASTM tests
  - E1153
  - E-2149
  - E2180
  - G21
- AATCC
  - Method 30, Part III
  - Method 100
  - Method 147
  - Method 174 Part 1
  - Method 174 Part 3
- Zone of inhibition
- Soil burial

There are many tests for anti-microbial effectiveness
Your antimicrobial vendor can help you with these tests

As of 2017, there are no internationally recognized standard methods for determining the efficacy of anti-bacterial plastics
Make sure your claims are not misleading or migrate into any health claim
Work closely with your supplier

As of 2017, there are no internationally recognized standard methods for determining the efficacy of anti-bacterial plastics
Make sure your claims are not misleading or migrate into any health claim
Work closely with your supplier
Key Considerations When Choosing an Anti-microbial Additive for Plastics

- Addition level to achieve objective
- Particle form and size
- In process stability with plastic
- Migration characteristics
- UV
- Heat stability of the antimicrobial
- Chemistry of the polymer
- Amount of active ingredient in the antimicrobial additive
- Stability in water
- Part design
  - Size
  - Shape
  - Wall thickness
  - Surface texturing
Regulatory – United States

- Antimicrobials/biocides are regulated by the Food and Drug Administration (FDA) if product claims that infection is reduced
- FDA studies are required for HAI claims

- Regulated by the Environmental Protection Agency (EPA)
  - under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
  - anti-microbial products must be registered with the EPA before they are sold
Regulatory - Europe

- In the EU, antimicrobials/biocides are regulated by the Biocidal Products Directive 98/8/EC adopted in 1998
- Directs every member states to have common procedures for evaluating and approving biocidal substances before 2008
- Formulators and manufacturers must apply for authorization
  - assessment studies
  - If product is approved in one member state it will be approved in all member states (Brexit complicates this)
Regulatory - China

- China has established their own regulations covering Food Contact and Antimicrobials
- Generally emerging countries borrow procedures and protocols from already established regions
- Key however is that many times they are DIFFERENT and one needs to stay abreast of specifics and most recent regulations
Claims Under Regulatory Exemption

• USA
  • “Treated Articles Exemption” (40 CFR 152.25)
    • you don’t have to register with the EPA if your claim states that the anti-microbial is a material preservation agent
      • “preservative to protect treated articles from microbial degradation”
      • “protection from odor-causing bacteria”
    • the product can’t make claims concerning personal or public health benefit unless rigorous FDA testing has been performed to prove this benefit…very costly

• Europe
  • specific products have to be registered (very costly)
  • registration can be avoided with claims similar to above under “Treated Article Exemption”
Medical Markets/Applications

- Minimally invasive medical products (<30 days in body use)
  - Central venous Catheters (CVC)
  - IV kits
- Endotracheal tubes
- Wound dressing
- Re-usable medical items
  - Hospital bedding
  - Dental trays
  - Beds
  - Hospital gowns
  - Orthopedic devices
  - Laparoscopic instruments
- Surgical drapes
- Syringes
- Many more
FOR FURTHER INFORMATION

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