Science meets industry – Why are many innovative coating technologies never entering the market?

AMiCI workshop March 20th 2018, Ljubljana

Dr. Simone Schulte
Evonik Resource Efficiency GmbH
We are almost everywhere. Even if you don’t see the Evonik brand, we make our daily lives a little better in many areas.
Nutrition & Care

Sales
€ 4,924 bn
Adj. EBIDTA / Margin
€ 1,435 bn / 29.1%

Resource Efficiency

Sales
€ 4,279 bn
Adj. EBIDTA / Margin
€ 896 bn / 20.9%

Performance Materials

Sales
€ 3,435 bn
Adj. EBIDTA / Margin
€ 309 bn / 9.0%

Animal Nutrition
Baby Care
Health Care
Personal Care
Household Care
Comfort & Insulation
Interface & Performance

Coating Additives
Silica
Crosslinkers
Silanes
Coating & Adhesive Resins
High Performance Polymers
Oil Additives
Active Oxygens
Catalysts

Acrylic Monomers
Acrylic Polymers
Performance Intermediates
Functional Solutions
Agrochemicals & Polymer Additives
CyPlus Technologies
One partner - many experts

Feature Markets

Automotive Interior
Rigid Packaging
Flexible Packaging Inks
Plastic Coatings
Antifouling

Heavy-Duty Coatings
Inkjet
Functional Exterior Coatings
Interior Wood Coatings
Automotive OEM Coatings
Competence Center for Smart Surface Solutions

Topics

- Anti-fouling
- Anti-icing
- Corrosion protection
- Anti-microbial
- Easy-to-clean
Evonik addresses these needs with the Smart Surface Solutions (S³) competence center

<table>
<thead>
<tr>
<th>Opportunity</th>
<th>Corrosion protection</th>
<th>Icephobic</th>
<th>Easy-to-clean</th>
<th>Anti fouling</th>
<th>Anti microbial</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D focus</td>
<td>Component toolbox for C4/C5 corrosion protection coatings, based on all available Evonik technologies</td>
<td>Elastomeric icephobic coatings with interfacial slippage</td>
<td>Coating components and formulations with low dirt pickup rate and easy-to-clean properties</td>
<td>Anti fouling coatings package, based on resins, particles and additives</td>
<td>Coating components and formulations with anti-microbial/anti-adhesive properties</td>
</tr>
<tr>
<td>Organization</td>
<td>• 6 interdisciplinary, experienced teams</td>
<td>• Close cooperation with most BLs of RE segment</td>
<td>• Close exchange with R&amp;D, tech service and marketing of BL Coating Additives, use of equipment</td>
<td>• Several co-operations with external partners (e.g. start-ups and universities)</td>
<td>• Close exchange with R&amp;D, tech service and marketing of BL Coating Additives, use of equipment</td>
</tr>
</tbody>
</table>

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Customers

Expect **easy to use, long-term, universal, non-toxic, non-hazardous and price efficient** technical solutions with no drawbacks to the coating properties.

Industry

Challenges:

- Several technologies available but often treated only one aspect of anti-microbial action
- Not all technologies are applicable in every application
- Interdisciplinary project teams are rare in industry
- Investments is high for a future uncertain market: time- and cost-intensive research plus regulatory demands
Overview Technologies

Accepted Manuscript

Surface Modifications For Antimicrobial Effects in the Healthcare Setting: A Critical Overview

Christian Adlhart, Joanna Verran, Nuno F. Azevedo, Hulya Olmez, Minna M. Keinänen-Toivola, Isabel Gouveia, Luis F. Melo, Francy Crijns

PII: S0195-6701(18)30062-8
DOI: 10.1016/j.jhin.2018.01.018
Reference: YJHIN 5334

To appear in: Journal of Hospital Infection

Received Date: 27 November 2017
Accepted Date: 25 January 2018
Wide variety of technologies for antimicrobial coatings and surfaces

<table>
<thead>
<tr>
<th>Technology</th>
<th>Antimicrobial loading</th>
<th>Photoactivated Surfaces</th>
<th>Polymeric binders</th>
<th>Micro/Nano structured</th>
<th>Antiadhesive Structures</th>
<th>Dispersin B</th>
<th>Lysostaphin</th>
<th>Probiotics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanism</td>
<td>Biocide</td>
<td>Photochemical cascades</td>
<td>Surface biocide</td>
<td>Settlement prevention</td>
<td>Surface recognition prevention</td>
<td>Enzymatic breakdown of biofilm</td>
<td>Biological biocide</td>
<td>Harmless biofilm crowds out harmful microbes</td>
</tr>
<tr>
<td>Advantage</td>
<td>State of the art, actives registered in BPR</td>
<td>Physical effect ➔ no BPR</td>
<td>No leaching</td>
<td>Physical effect ➔ no BPR</td>
<td>Physical effect ➔ no BPR</td>
<td>biological</td>
<td>biological</td>
<td>biological</td>
</tr>
<tr>
<td>Dis-advantage</td>
<td>Leaching, resistance, adaption, overgrowth, BPR</td>
<td>Needs UV, Degradation of organic components of coating</td>
<td>Overgrowth, resistance, no cleaning, BPR, only active in cationic binders</td>
<td>Stability, only on dry surfaces, nanotoxicology</td>
<td>Realisation, stability, evaluation influence of dirt missing</td>
<td>Realisation, up-scale, very specific, only in humid and mild environments</td>
<td>Realisation, up-scale, very specific, only in humid and mild environments</td>
<td>Realisation, up-scale, care, stability, microbial community not predictable</td>
</tr>
</tbody>
</table>

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# Regulations

If a product or solution falls under a biocide regulation, the market introduction will be expensive and complex.

<table>
<thead>
<tr>
<th>Country/Region</th>
<th>Relevant Authority</th>
<th>Regulation</th>
<th>Cost for registration</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>U.S. Environmental Protection Agency (EPA)</td>
<td>Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)</td>
<td>$1.5 – 5 m</td>
<td>Master files with registration data for biocides are valuable assets for existing players, and a tough market entry hurdle for new entrants</td>
</tr>
<tr>
<td>Europe</td>
<td>ECHA</td>
<td>Biocidal Products Regulation (BPR) EU 528/2012 Medical Device Regulation (MDR) EU 745/2017</td>
<td>€3 – 6 m</td>
<td>Market players are forced by law to share their registration data, new entrants may buy into consortia like structures</td>
</tr>
<tr>
<td>Japan</td>
<td>Ministry of Economy, Trade and Industry (METI)</td>
<td>Law Concerning the Examination and Regulation of Manufacture of Chemical Substances</td>
<td>t.b.d.</td>
<td>At least general registration of substances, which is costly</td>
</tr>
<tr>
<td>China</td>
<td>3 different ministries</td>
<td>15+ different regulations</td>
<td>t.b.d.</td>
<td>Very complex legislation and regulation due to missing overall standard</td>
</tr>
</tbody>
</table>

If a product or solution falls under a biocide regulation, the market introduction will be expensive and complex.

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Remember meeting in Pori
BPR progress

Start: "new molecule"

Goal: Registered active agent
Entry union list

2018
Start: Dossier
ECHA: Check
EU-Authorities: Check
Possibly additional tests
Evaluation of the authorities
Evaluation of BPC of ECHA
BPC statement
EU-Commission (COM): Decision

2022
2023
2024

1000
500
500
?
?
?

kEuro

∑ ~ 6 years
∑ ~ 3 Mio €

Start: Registered active agent

Goal: Approved biocidal product families for PT 2 in Europe

2027

Approval for PTs and countries
COM implementing regulation
PT dossier for product family
COM: Decision
Admission fee for the next ten years

500
?
150
?
200

kEuro

∑ ~ 3 years
∑ ~ 2 Mio €
Supply chain coating additives

Additive supplier e.g. Evonik, Croda, RAS,…

Active agent registered

Coating manufacturer e.g. ppg, Sherwin Williams, AkzoNobel, …

Biocidal Product registered

Enduser e.g. hospitals, public transportation, toys, automobile interior, …

Treated article labeled

Do our customers want to spend 3 years and 2 Mio € for one biocidal product (family)???
Do sensitive customers want to label their products???
What does that mean for the development of new anti-microbial actives?

- Only big companies can afford the registration process
  - Nearly impossible for start-up companies or university spin-offs
- Way away from anti-microbial actives towards physical effects:
  - Physical actives (UV)
  - Antiadhesive structures
  - Easy to clean surfaces
Lack of standardised methods for testing under representative environmental conditions

What do we want to measure???

Antiadhesive?

Easy-to-clean?

Dead bacteria

Living bacteria in dirt matrix

Surfaces with contact biocide

Base layer

Living bacteria in dirt matrix

Surfaces with soluble biocide

Base layer
Standard test methods (selection)

- ASTM E 2180, 2001 Standard test method for determining the activity of incorporated antimicrobial agent(s) in polymeric or hydrophobic materials. Agar overlay test
- EN 15457:2014: Paints and varnishes - Laboratory method for testing the efficacy of film preservatives in a coating against fungi
Standard tests (selection)

- JIS Z 2801:2000-12-20 Antimicrobial products - Test for antimicrobial activity and efficacy
- JIS L 1902:2002 Testing antibacterial activity and efficacy on textile products
- ISO 22196:2011-08 Measurement of antibacterial activity on plastics and other non-porous surfaces
  - Difficult with hydrophobic surfaces ("pill off")
  - Cultivation methods
  - Short term max 24 h
  - Pure cultures: clinical strains
  - No contamination
  - Not applicable with anti-adhesive surfaces, restricted applicable with e.g. polymeric binders
  - Practical relevance???
First approach for testing under representative environmental conditions
Imagine it is scientifically proven that the reduction of pathogens on surfaces is more efficient with
• AMCs and cleaning with water than
• Conventional coating and treating with disinfectants?

Benefits:
• Less resistance problems
• Less use of toxic disinfectants
• Environmentally friendly

BUT

„Conservative“ industry open for innovation?

- Medizinprodukte-Betreiberverordnung (operator)
- Medical Device Directive (MDD) 93/42/EWG
- Medical Device Regulation (MDR) (EU) 2017/745
- Medizinprodukte Gesetz (MPG)
- KRINKO / BfArM Empfehlung, Anforderung an die Aufbereitung
- KRINKO Empfehlung, Flächenhygiene
- Vom Medizinprodukt-Hersteller bereitzustellende Informationen für die Aufbereitung von Medizinprodukten
- ISO/NP 17664-2 Part 2: Medical devices not intended for direct patient contact
- DIN EN ISO 14971:2013
- Anwendung des Risikomanagements auf Medizinprodukte
- DIN Entwurf zur Krankenhausreinigung
Good exchange of science and industry necessary

Co-operation in research projects at an earlier stage

Try to take all aspects into account not only the technical ones
If a product or solution falls under a biocide regulation, the market introduction will be expensive and complex: BPR- Product Classes of Interest

<table>
<thead>
<tr>
<th>PT 2</th>
<th>Disinfectants and algaecides not intended for direct application to humans or animals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs. Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities.</td>
</tr>
<tr>
<td></td>
<td>Used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil.</td>
</tr>
<tr>
<td></td>
<td>Used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials.</td>
</tr>
<tr>
<td></td>
<td>Used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.</td>
</tr>
</tbody>
</table>

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<tr>
<th>PT 7</th>
<th>Film preservatives</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PT 8</th>
<th>Wood preservatives</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms, including insects. This product type includes both preventive and curative products.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PT 9</th>
<th>Fibre, leather, rubber and polymerised materials preservatives</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration. This product type includes biocidal products which antagonise the settlement of micro-organisms on the surface of materials and therefore hamper or prevent the development of odour and/or offer other kinds of benefits.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PT 10</th>
<th>Construction material preservatives</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Used for the preservation of masonry, composite materials, or other construction materials other than wood by the control of microbiological and algal attack.</td>
</tr>
</tbody>
</table>

Each PT is having immense testing protocol necessary for later registration by raw material supplier

Case-by-case each treated article also has to be registered by customer
First solutions for antimicrobial coatings are offered to the market using existing technologies

**Encapsulated biocides**
- Wall paints with encapsulated low molecular biocides, e.g. quats, BIT/MIT
- Capsules either break up in the drying process or are porous
- Examples: Sherwin Williams Paint Shield, STO exterior wall paints…

**MyCroFence by CRODA**
- Antimicrobial cationic polymer
- No leaching

**Nano silver**
- Nanoscale silver as active biocide in coatings, fibres etc.
- Controlled release of silver results in leaching of silver to the surface
- Examples: Silverguard (McGill), RAS Materials
First solutions for antimicrobial coatings are offered to the market using existing technologies

Encapsulated biocides

• Wall paints with encapsulated low molecular biocides, e.g. quats, BIT/MIT
• Capsules either break up in the drying process or are porous
• Examples: Sherwin Williams Paint Shield, STO exterior wall paints…

Surface topography/pH value

• Example: Viessmann SmartProtect
• Antimicrobial powder coating for professional freezers
• Undisclosed technology, antimicrobial effect achieved through pH value, surface energy and surface topography
• Seems to be biocide free

Nano silver

• Nanoscale silver as active biocide in coatings, fibres etc.
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• Examples: Silverguard (McGill), RAS Materials

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