compounding WORLD

July 2013

TAKE A CLOSER LOOK AT COLOUR

ANTIMICROBIALS IN ACTION

MELT FILTRATION DEVELOPMENTS

THE LATEST TRENDS IN TPEs

Rethinking biocides for plastics

Antimicrobials continue to play an important role in protecting plastics from damage by microbes, including bacteria, algae and fungi such as mould and mildew.

However, the types of chemistries that are used for biocides compounded into plastics are undergoing major changes with the phase-out in Europe of the traditional workhorse biocide, OBPA (oxybisphenooxyarsine), due to concerns about the toxicity and ecotoxicity of arsine chemistry. Supply of OBPA to the EU market ended as on 31 January 2013 under the Biocidal Products Directive (BPD).

Although there are several alternatives, none are equivalent to OBPA. Depending on the microorganism, the alternatives may not always be effective or may require different levels of active ingredient to be effective. Formulations using alternatives may need to be modified to ensure that they are stable and provide maximum cost efficiency. Suppliers and their customers have been preparing for years for the potential need to replace OBPA, but it is still a major undertaking.

Although OBPA supply is currently allowed in the United States, its use is coming up for a re-registration eligibility decision (RED) with the US Environmental Protection Agency (EPA) in 2014. This re-registration is being backed by OBPA supplier **Troy Corporation**. Its customers in all regions except Europe can continue to use OBPA without any service interruptions, says David Faherty, the company's vice president.

The phase-out of some well-established biocides means that compounders are turning to alternative antimicrobials both to protect plastics and to reduce hospital acquired infections. **Jennifer Markarian** reports

However, the leading suppliers of OBPA, Akcros and Dow, are not supporting the RED. Akcros and Dow formed a strategic partnership on biocides in North America in November 2012. Under the agreement, Akcros is the exclusive channel partner for Dow Microbial Control's OBPA and isothiazolinones for the polymer markets in the US and Canada, promoting grades under the Intercide brand. Akcros plans to continue to supply OBPA as long as permitted into 2014 and as stock allows, says Dean Nichols, biocides

Sanitized's new PL 12-32 has high water resistance and UV stability for outdoor PVC applications

product manager for **Akcros**.

Several chemistries can be used as alternatives to OBPA in plastics. The primary options are the well-established isothiazolinones, which include n-octyl-isothiazolinone (OIT), dichloro n-octyl-isothiazolinone (DCOIT), and others, such as butylbenzisothiazolinone (BBIT). Other alternatives include Folpet, zinc pyrithione, silver and iodo-propynlbutyl carbamate (IPBC).

Evaluating alternatives

When choosing a biocide, formulators need to look at the spectrum of efficacy against various types of microbes and at the cost to dose at the level needed for efficacy. One measure is minimum inhibitory concentration (MIC), which shows inherent activity of the biocide against a particular microorganism.

Another measure, not shown by MIC, is the availability of the active ingredient on the plastic surface, which depends on several factors, including the dosing level and the biocide's migration rate through the finished plastic part.

The migration rate is affected by the water solubility of a biocide. Although it is necessary for the active ingredient to migrate to the surface to be effective, if it migrates too quickly it can lose efficacy over time. Highly water-soluble actives may show visually impressive zones in agar plate tests, but are more prone to leach out of plastics more quickly than often desired, especially in exterior and high-moisture applications, notes Nichols. Conversely, low water-soluble actives, such as silver and DCOIT, don't show such zones in agar plate tests, which, Nichols warns, can lead to improper conclusions that they cannot be effective.

Other important biocide properties include heat stability, UV stability, and interaction with other additives in a formulation. "To achieve the performance and especially the price/performance of OBPA is quite challenging," says Dr Heinz Katzenmeier, head of innovation at **Sanitized**. While no single substance is ideal for all applications, properties can be optimized for a specific application's requirements.

Improving stability

Sanitized recently introduced two new products for PVC with improved stability in specific applications. Sanitized PL 12-32 has high water resistance and UV stability, making it suitable for outdoor applications. Sanitized PL 12-33 has high thermal stability to withstand high processing temperatures while retaining transparency; it is targeted for indoor applications, such as flooring and furnishings. Both formulations are designed to reduce initial discoloration and yellowing in use. Katzenmeier says that these combinations of active ingredients are fully able to replace OBPA in the relevant applications.

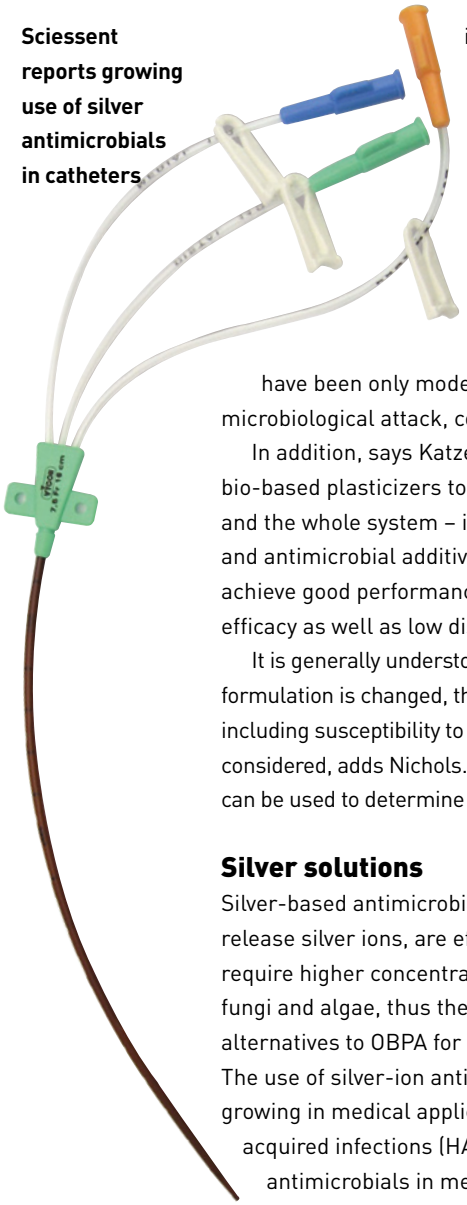
Another new product, Sanitized PL 25-36, is a clear solution with no dispersed particles that is compatible with various polymer matrices, such as PU or PVC. The patent-pending product causes no turbidity and is designed for applications where high clarity is demanded, such as PVC curtains or indoor flooring. A field test at the University of Manchester is currently underway with PVC flooring containing PL 25-36 to demonstrate efficacy under real conditions, and results to date have exceeded expectations, says Katzenmeier.

In addition to efficacy and stability, formulators must consider potential interactions with other additives, such as heat stabilizers, antioxidants, and light stabilizers, says Nichols. He adds that Akcros, which produces a wide variety of additives for PVC, has carried out extensive development work to solve interaction issues. One of these solutions is a new "isothiazolinone-friendly" stabilizer for flexible PVC. Initially these products are available in the EU, but similar products are being rolled out for the US market, says Nichols, who notes that Akcros is also developing stabilizers that are "friendly" to other biocides.

Katzenmeier notes that Sanitized has built up an empirical database that is used to check for expected interactions between recommended antimicrobials and the stabilizer used by a customer. Sanitized has also started a publicly funded project with an academic institution that will scientifically investigate these complex interactions.

Some bio-based plasticizers, such as soybean-oil derivatives, levulinic ketals, glycerol esters, and

Sciessent reports growing use of silver antimicrobials in catheters



isosorbid diesters, are more susceptible to microbial attack compared to conventional, phthalate-based plasticizers. Users who switch to natural plasticizers may require higher levels of biocide, or, in some cases, may need to introduce biocides to products that previously may have been only moderately or even unsusceptible to microbiological attack, comments Nichols.

In addition, says Katzenmeier, the tendency of some bio-based plasticizers to cause discoloration is higher, and the whole system – including plasticizer, stabilizer and antimicrobial additive – must be fine-tuned to achieve good performance in terms of antimicrobial efficacy as well as low discoloration.

It is generally understood in the industry that when a formulation is changed, the impact on all properties, including susceptibility to microbiological activity, must be considered, adds Nichols. Microbiological laboratory tests can be used to determine differences in susceptibility.

Silver solutions

Silver-based antimicrobials, primarily those that release silver ions, are effective against bacteria but require higher concentrations to be effective against fungi and algae, thus they are not seen as cost-effective alternatives to OBPA for traditional plastic protection. The use of silver-ion antimicrobials is, however, growing in medical applications. Awareness of hospital acquired infections (HAIs) has led to increased use of antimicrobials in medical devices and other surfaces in healthcare settings, such as masks, gowns, equipment and furnishings.

Silver has a long history of efficacy against bacteria, and has been found to be effective against antibiotic-resistant organisms, such as MRSA. This was covered by Lise Moloney, director of business development for healthcare at **Sciessent**, in a February 2012 article in Compounding World on 'Specifying silver antimicrobials for medical devices' (**http://bit.ly/sciessent**).

"We continue to see interest in all the major device-related infection areas: central venous catheters and accessories to central lines (like connectors), urinary catheters, endotracheal tubes and wound dressings and closures," reports Moloney. "I think the biggest use and greatest success of antimicrobials in FDA-cleared devices has been in central venous catheters, where the pathogenesis of catheter-related bloodstream infection is well understood and accepted. The need to prevent microorganisms from colonizing the external and internal surfaces of the catheter is critical to preventing these infections." Data published in 2012, for example, found a 90% reduction in catheter-related bloodstream infections using Agion-treated umbilical venous catheters in pre-term infants. There is also an increasing interest in antimicrobials for surfaces in patient-care areas. Adoption in these applications has been slower because it is harder to demonstrate the direct benefit of treating these types of surfaces and to achieve regulatory clearance for claims against human pathogens than it is with indwelling medical device, says Moloney.

"Purchasing groups and infection-control practitioners want to know what the benefit will be before they switch to an antimicrobial product. We will see greater demand and acceptance for these products as more data is generated to show a link between surfaces in the healthcare environment and patient outcomes," predicts Moloney. Other areas of growth for silver antimicrobials, outside of healthcare, include food and water products, she adds.

BASF, which offers Irgaguard silver-ion antimicrobials for industrial applications, supplies fully compounded polymer systems containing medical-grade, silver-ion releasing HyGentic additives for medical

EU labelling requirement changes

The Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) will replace the Biocidal Products Directive (BPD) on 1 September 2013. As in the previous directive, the approval of active substances takes place at Union level and the subsequent authorisation of the biocidal products at Member State level. This authorisation can be extended to other Member States by mutual recognition. The new regulation also allows for Union-level authorisation.

The BPR includes a requirement (Article 58) that articles treated with biocides must be labelled as such and must include the chemical names of the active substances and what function they have. In addition, the regulation requires that claims must be substantiated. While some documents note an implementation date of September 2016, this date applies to yet-unregistered active ingredients, and the labelling requirements are expected to go into effect 1 September 2013 for treated articles made in or imported into the EU. For details, visit: **http://bit.ly/biocide**

applications. Grades include HyGentic SBC (styrene butadiene copolymer), HyGentic PA (glass-filled nylon) and HyGentic SA (acrylic modified polystyrene); custom formulations can also be developed in a wide range of plastic materials.

BASF is currently developing products that provide added functionality beyond antimicrobial performance, says Stephen Zlock, business development manager for medical device materials at the company. For example, a polyurethane compound with both anti-thrombotic and antimicrobial performance for vascular access devices is in advanced development.

PolyOne's WithStand antimicrobial additive solutions, available since 2010, are targeted for medical devices, medical packaging, and other healthcare applications. Last year, PolyOne launched Smartbatch HC additive concentrates, which combine WithStand antimicrobials and OnColor HC colorants for healthcare applications.

Last year **Clariant** added Sanitized MedX silver antimicrobials, which can also be combined with pigments, to its line of Mevopur masterbatches for medical applications. Targeted applications include catheters, surgical instruments, and preservative-free pharmaceutical packaging.

Plastics Color Corporation (PCC) recently introduced silver-ion based MicroBlok antimicrobial compounds targeted for medical device, medical packaging, appliance and other consumer markets. Fred Jhaveri, PCC's global technical manager, says that the additive inhibits the growth of bacteria which may cause stains, odours and product deterioration.

Nano-technology options

NanoBioMatters' BactiBlock additive is a silver-ion based technology in a nanoclay carrier. The antimicrobial has been used in Europe commercially since 2010 and received EPA registration for use in the US in 2011. The primary difference between BactiBlock and other silver-based solutions is the clay carrier, which has a synergistic effect and works as an efficient delivery system with long-term durability, says Paul Kennedy, business development manager for North America at NanoBioMatters. The ionic silver is linked to the clay surface, which creates a uniform distribution of the active species and prevents platelet agglomeration to ensure additive dispersion throughout the polymer matrix. Several BactiBlock grades are available for a range of polymers and applications.

Last year, compounder **RTP Company** announced that it would use BactiBlock in antimicrobial compounds targeted for applications including furniture, athletic equipment, personal-care items, office supplies, healthcare environments, housewares and others. RTP Company uses various organic and inorganic antimicrobial additives in its masterbatches and ready-to-use compounds to meet the needs of specific application requirements.

RTP is using NanoBioMatters' BactiBlock, which combines silver-ion technology and a nanoclay carrier

Earlier this year, **Sabic** launched nine new antimicrobial compounds featuring silver technology. The company says that they have been tested for log reduction values according to ISO 22196-2007. Five of the grades provide a high antimicrobial effect with log reduction values above 4, representing more than a 99.99% reduction in pathogens. The other four compounds have a lower antimicrobial effect with log reduction values below 4, representing a 99.0 to 99.99% reduction in pathogens.

The new grades are based on the four Sabic resins that are most commonly used in medical devices: Lexan EXL copolymer, Lexan PC, Xenoy PC/PBT, plus PP resins with and without glass fibre reinforcement. The company says that its optimised antimicrobial compounds offer advantages over adding antimicrobial masterbatch to a base resin, including more uniform distribution of the active ingredient. It also says that its expertise in colour and effects means that it can provide precise control over clarity, a property that can be impacted by antimicrobials.

Target applications include fluid and drug delivery systems, surgical instruments, monitoring and imaging devices and durable medical equipment such as

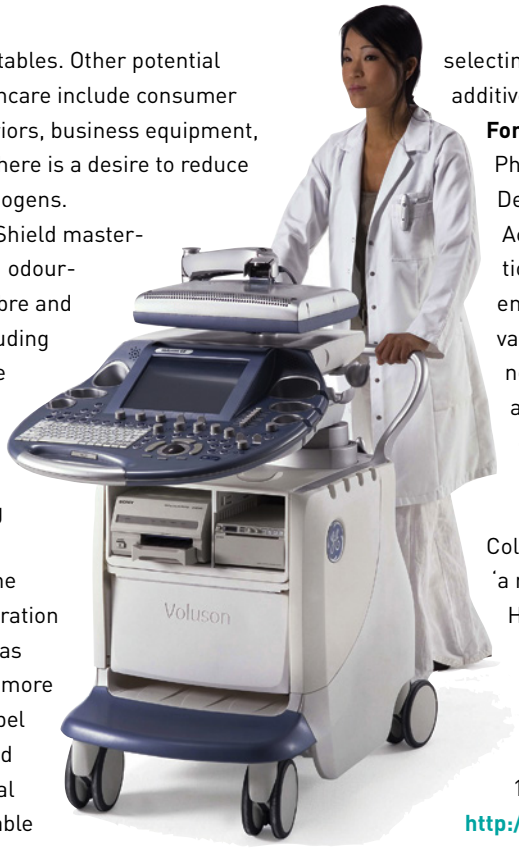
Sabic's new antimicrobial compounds can be used for medical equipment like healthcare scanners

hospital beds and operating tables. Other potential applications outside of healthcare include consumer electronics, automobile interiors, business equipment, or any other surface where there is a desire to reduce the potential transfer of pathogens.

Americhem introduced nShield masterbatches in 2012 for inhibiting odour-causing bacteria growth in fibre and plastics for applications including synthetic turf and automotive interiors. Americhem says that the additive is non-migratory and resists discoloration for long-lasting aesthetic appeal.

Troy's Faherty says that the company has seen some migration away from silver and that it has introduced alternatives, with more in development. Troy's Micropel 1000, for example, is designed to impart surface antibacterial properties and offer comparable performance to silver but in a more cost-efficient manner, says the company.

Foster Corporation supplies custom formulations of medical-grade polymers containing either silver or polymeric-based antimicrobial compounds that reduce bacterial infection in catheters and sustained bodily fluid contact applications. Last year, Foster announced a partnership with Biosafe to develop and market Biosafe's polymeric additive technology based on cationic quaternary ammonium salt, which is seen as a cost-effective alternative to silver additives for infection-resistant medical devices.



More information

Lise Moloney, director of business development for healthcare at Sciessent, will present a paper on selecting and applying antimicrobial additives at the **Compounding World Forum 2013**, which is being held in Philadelphia, PA, USA on 10-11 December. In addition, Dr Larry Acquarulo, CEO of Foster Corporation, will give a paper at the event entitled 'Adding functionality and value to medical compounds with novel reinforcements, fillers and additives'. For more information on the conference, visit http://bit.ly/CWF2013p.

Dr Manish Nandi and Lynn Colucci-Mizenko of Sabic will discuss 'a multi-pronged approach to meeting HAI challenges with specialty engineered thermoplastics' at the **Medical Grade Polymers 2013** conference, which takes place in Boston/Woburn, MA, USA, on 17-18 September. For details, visit http://bit.ly/MGP13.

Click on the links for more information:

- **www.akcros.com**
- **www.americhem.com**
- **www.basf.com**
- **www.biosafe.com**
- **www.clariant.com**
- **www.fostercomp.com**
- **www.nanobiomatters.com**
- **www.plasticscolor.com**
- **www.polyone.com**
- **www.rtpcompany.com**
- **www.sabic.com**
- **www.sanitized.com**
- **www.sciessent.com**
- **www.troycorp.com**