

Antimicrobials in Plastics: Current EPA Issues

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Regulatory Aspects of Antimicrobials in Plastics

- Treated Articles
 - Scope of Exemption
 - Imports
- Active Claims
 - Recent Activities
 - Going Forward
- European Regulation

Treated Article

- An article or substance treated with, or containing, a pesticide to protect the treated article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for that use. See 40 CFR sec. 152.25(a).

Treated Article Exemption

- 40 CFR sec. 152.25(a) provides an exemption from all requirements of FIFRA for qualifying articles or substances treated with, or containing, a pesticide if:
 - The incorporated pesticide is registered for use in or on the article or substance, and
 - The sole purpose of the treatment is to protect the article or substance itself.

Plastic as an Exempt Treated Article

- Plastic containing an antimicrobial qualifies as a “treated article” if:
 - The pesticide contained in the plastic is *registered by EPA* for such use, and
 - The pesticide is present only to preserve the plastic, and
 - The only claim for the article or substance is that the plastic is preserved.

Treated Articles – Acceptable Claims

- Mold and mildew resistant claims:
 - “Mildew resistant”
 - “Gives mildew-resistant coating”
 - “Resists mold and mildew staining”
- Odor resistant claims:
 - “Inhibits the growth of bacterial odors”
 - “Odor resistant”

Claims falling outside the Treated Article Exemption

- Any claims for the pesticide beyond preservation of the plastic substance or articles.
- These can be:
 - public health claims; or
 - claims to protect another material

Public Health Claims that will Trigger A Requirement for Registration

- “Fewer colds”
- “Stops spread of disease”
- Any claim against infectious or pathogenic microorganisms such as *E. coli*, *HIV*, *mycobacterium tuberculosis*, *salmonella*, *pseudomonas aeruginosa*, *streptococcus* or *staphylococcus aureus*.
- This shower curtain (bath mat) kills athletes foot fungus.

Protection of Another Material Claims that will Trigger a Requirement for Registration

- This coating will protect the material being coated from mold, mildew and decay causing organisms.
- Emerging exception to this for “Barrier Claims”
 - Barrier must prevent pest entry, contain no toxicant.
 - EPA requires data to verify
 - Timbersil non-wood preservative is considered a barrier.

Registration of Antimicrobial Articles

- Any active treated claims for the product requires registration with EPA.
- If public health claims are made, efficacy data must be submitted to EPA to support registration.

Is EPA Serious?

- EPA has taken enforcement actions against companies selling products with claims beyond those allowed for treated articles.

Recent EPA Enforcement Actions

- ❑ EPA took action against ATEN Technology, Inc., acting for its subsidiary IOGEAR, selling unregistered pesticides and making unproven claims about their effectiveness.
- ❑ IOGEAR made claims that its computer peripherals (wireless laser mouse with nano shield coating, laser travel mouse with nano coating technology, and wireless RF keyboard and mouse combinations) protected users against germs.

Recent EPA Enforcement Actions

- EPA took action against Target Corp. for selling and distributing unregistered pesticides from its stores and on its Web site.
- At issue were antimicrobial toilet seats, mattress pads and pillows.
- The toilet seats, mattress pads and pillows made "germ-killing" claims.

An Interesting Issue: Imports

- For example, consider an imported plastic shower curtain:
 - No claims – no requirements
 - Claim of mildew resistance – provided the pesticide used to treat the curtain is registered with EPA, the curtain is an exempt treated article. (Registered AI or product required?)
 - Claim of mildew resistance with an unregistered biocide – the curtain must be registered.

Another Interesting Issue: Treated medical devices

- Medical devices, such as surgical drapes and endoscopes, fall under dual EPA/FDA jurisdiction.
- Antimicrobials used in medical devices as preservatives must be registered for such use by EPA
- EPA plans to transfer all jurisdiction for medical device uses to FDA, but has not yet published its proposal
- Antimicrobials that are intended to be released by a medical device to prevent infection are regulated by FDA as drugs

The most interesting new development: Innovative Efficacy Claims for Active Surfaces

- EPA recently approved registration of five copper-based alloy products with limited public health claims.
- The products are solid sheets to be fabricated into articles such as door knobs, counter tops and hand rails.
- The products make claims to kill 99.9% of bacteria within two hours and may only be used as a supplement to standard infection control practices.

The most interesting new development: Innovative Efficacy Claims for Active Surfaces

- The registrations include special conditions, including obligations to ensure the products are used properly.
- All advertising materials must be submitted to EPA for review.

The most interesting new development: Innovative Efficacy Claims for Active Surfaces

- ❑ **What do the these Registrations tell us?**
- ❑ With adequate documentation, EPA is willing to entertain and approve efficacy claims that are factually accurate but not within established categories
- ❑ This can extend to public health organisms and claims.
- ❑ Other compounds may be amenable to similar claims
- ❑ EPA may now be willing to register articles that make claims of antimicrobial activity based on incorporated antimicrobials
- ❑ Question whether trend will continue with new management at AD.

REACH: Treated Plastics in the EU

- *Active substances* manufactured or imported for use only in biocidal products have narrow exemption from (pre-)registration but does not cover co-formulants in the preservative. Badly drafted and most companies are (pre-)registering anyway.
- Treated articles face either:
 - **(Pre-)Registration:** ‘intended to be released under *normal or reasonably foreseeable* conditions of use’. (Avoid importing substances/preparations into EU for assembly.)
 - **Notification:** SVHCs with ‘exposure to humans or the environment during normal or reasonably foreseeable conditions of use *including* disposal’. (Can you exclude exposure?)

BPD: Treated Plastics in the EU

- Preservatives in articles or preparations entering the EU are not currently covered by the BPD if the preservative effect is internal and no external effect claim is made. (No treated article exemption *per se*)
- European Commission recognizes this “loophole” and plans to address in upcoming BPD revision (*est.* 2013).
- Making preservative *claims* triggers the BPD.
- If an article is treated and there is an external effect you can only use an active substance under review in the EU (Annex II to Reg. 1451/2007).

Additional Information - EPA

- Additional information is available at:
 - EPA's PR Notice 2000-1 at http://www.epa.gov/PR_Notices
 - Treated article factsheet at <http://www.epa.gov/opp00001/factsheets/treatart.htm>
 - 40 CFR sec. 152.25(a) at <http://ecfr.gpoaccess.gov>

Additional Information: REACH Beyond Pre-Registration, *Complimentary Webinar*

- **9 December 2008, 1600 - 1730 CET (1000 AM EST)**
- **Led by:** Steptoe REACH Team and guest speaker, Malachy Hargadon, Environment Counselor, Delegation of the European Commission to the United States
- **Topics:**
 - Taking stock of pre-registration
 - Options in the event of pre-registration deficiencies
 - What's next?
 - Managing SIEF/Consortia activities
 - Data/cost-sharing in practice
- **To Register:**
<http://www.steptoel.com/REACHweb4>
- **REACH Resource Centre:** <http://www.steptoel.com/REACH>

So what will the future hold for antimicrobials in plastics?



So what will the future hold for antimicrobials in plastics?

- Stable treated article exemption
- Surveillance and enforcement for excessive statements
- Possible route to register active surfaces

Opportunities!

