



Q & A: Emerging Cosmetics Industry Regulations and Trends

Thursday, February 13th at 2pm EST

Question: While we as formulators don't use Bisphenol-A (BPA), some of the containers, closures, and other packaging components could contain BPA.

Answer: BPA is a monomer and is not used as a cosmetic ingredient. Plastic packaging made with polymers containing BPA as one of the monomers, can have trace residual levels of free monomers. In this case, testing for the BPA monomer can be conducted in the product using either HPLC or GC-MS techniques. This would be recommended on samples nearing the end of their shelf-life through real-time or accelerated stability studies. A formulation review of products' packaging can also be performed to determine whether testing is necessary.

Question: What is the current FDA position on triclosan? Is the FDA still waiting for the studies to be submitted before making its position?

Answer: Triclosan is not prohibited as a cosmetic ingredient. It is currently Category III for HealthCare Antiseptics for cleansers only. It is also an approved NDA for use in certain toothpastes.

Question: Can an OTC drug ingredient be included in a cosmetic as an inactive ingredient with no claims and still be considered a cosmetic?

Answer: Yes, as long as it has a cosmetic purpose. Mineral oil is a laxative and a skin protectant but used in many cosmetics as an emollient. However if certain OTC active ingredients (such as clonazepam in a cream) were to be used in a cosmetic, the FDA would consider this a drug regardless of claims, as it has no cosmetic purpose.

Question: Is the testing required in ISO 22716 supposed to be performed by the manufacturer or can it be subcontracted?

Answer: Testing can be performed either by the manufacturer or an "Approved" subcontractor. By approved, ISO 22716 says you must have a quality agreement with your supplier, an audit program in place and must verify your suppliers' use approved methods in testing against raw material and finished product specifications.

Question: What testing is required for cosmetics under ISO 22716?

Answer: Raw materials and packaging materials can be accepted on the basis of the suppliers' certificate of analysis (C of A) only if there are established technical requirements, experience and knowledge of the supplier, a supplier audit and agreement of the supplier's test methods. Finished goods should be sampled and tested by the quality control department. They should be tested and approved via qualified test methods and procedures.