Board Member Spotlight

Cosmetics- The Production of Safe Products

By Dr. Robb Akridge, Co-Founder & President, Clarisonic/L'Oreal Luxury Division

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Recent buzz from media and special interest groups suggesting cosmetic products are not safe seems to be in contradiction to the majority of consumer attitudes and purchasing habits.

So what procedures and regulations are in place already to ensure safe products? Contract Manufacturers (CM) have multiple screens and checkpoints during the production of products, as well as, guidance from federal agencies on the manufacture of these products. Historically, this has resulted in few issues with consumers. When rare issues have appeared the cosmetics industry self corrects rapidly.

In 2003 my company started a project to create our own cleansers. As part of this journey we shopped around for CM. Here are a few of the comforting procedures and processes already in place we encountered when visiting potential manufacturers which give support to assuring that cosmetic products are safe:

• Regulatory Affairs
Manufacturers either have a regulatory affairs expert on staff, or the owner is keenly aware of the regulations (state and federal) when it comes to ingredients allowed and testing needed to release a safe product.

• GRAS
As paraphrased from the FDA website (http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/), " 'GRAS' is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act, any substance that is intentionally added to food is a food additive that is subject to premarket review and approval by the FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive." Although typically viewed as a list of safe ingredients in the food industry, many are used in cosmetics. The GRAS information on the ingredients is based on true science to educate and guide the end user on how best to use them.

• Quarantine
Contract manufacturers get their raw ingredients from chemical suppliers. Upon receiving raw ingredients the manufacturer typically quarantines them until it is confirmed that the ingredient is what it says it is. Once the MSDS (Material Safety Data Sheet) is reviewed, and the quality specifications are confirmed, the ingredient can be released to the production floor for use. This prevents any wrongly labeled ingredients from getting into a formulation.

• Water Quality
Because the majority of liquid products are mostly water, the quality of the water is critical. Often times the water coming from the municipality may be good enough to drink but is still not good enough for cosmetic products. The manufacturers are proud to show the purity records of their water, and how this precious commodity is treated and stored prior to being used in formulas. Absense of heavy metals and safe microbial levels are critical information needed before the water can be used.

Once the final formulation is completed an entirely different set of evaluations occur to ensure product safety. Individual ingredients have their own chemical characteristics and behaviors, however, when put into a mixture to create a new product that new product has its own unique profile. So the following evaluations are usually performed in parallel:

• Material Compatibility and Stability
The chemical interaction of the end product with the container and lid is tested. These tests confirm that the container material is compatible with the formula and it will not chemically degrade over time. Accelerated testing is often used where the final retail product is placed in extreme temperatures to shorten the time needed to see any potential issues. Over the Counter (OTC) products are a differ-

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ent topic (not elaborated on here) and have their own highly rigorous FDA regulations.

• Ship Testing
Product in its final packaging may undergo a physical obstacle course of shaking and dropping to simulate shipping to ensure no leaks and thus avert potential environmental hazards.

• Microbial Content
Microbial content (or the lack of it) in water and final formulation is a key requirement for cosmetics safety. Two common microbial methods are used. Samples are analyzed to determine how many microbes exist in a certain volume. Based on the number of CFU (colony forming units) allowed by industry standards the sample either passes or fails. Often times samples are cultured and incubated to promote microbial growth. Another approach is microbial challenge. Because time tested preservative systems are under fire, new preservative systems are often tested by adding a known CFU to a sample and then monitoring the bacterial level over time. Bacterial increase would indicate a weak preservative.

• Safety Testing
In order to test how the formulation interacts with human skin, a Patch Test Study is conducted to make sure no issues occur when the product is in contact with the skin. In this study the formula is sent to a contract research organization (CRO) where it is applied to test subjects' skin (usually the back or forearm) using standardized long term exposure protocols. These controlled evaluations will determine if the formula is irritating. Once the microbial tests and patch tests are completed another series of safety tests can be conducted-- Long Term Safety Studies. This entails conducting daily at home use trials with many subjects over at least a 12 week period. All issues (if any) are recorded and used to evaluate the go-no go launch of the product.

Just to be clear, the steps above do not always fall under the contract manufacturers' responsibility. Often the brand owner does patch testing, microbial challenge, and long term usage with a CRO. So if everything mentioned so far isn't good enough to ensure safety, floating above all of these processes is the FDA who has the power to walk into any brand and/or CM and investigate any step of production or claims. An FDA visit can be prompted by complaints sent to them, what they observe on your website, or just because you fall on their annual review list.

The items I listed above are in the context of independent contract manufacturers. When it comes to large, publically traded multi-brand corporations there may be even tougher restrictions to ensure safe products. After all, they do not want to do anything that they or their shareholders would find risky or unsafe.

One final observation: Contract manufacturers (whether large or small) are often demonized as machines that want to make money. However, when you get to know the people that own and run these companies you'll find that they want to do the right thing which is to provide beautiful and safe products for their consumers. In the end, aren't the contract manufacturers consumers too?

Robb Akridge, PhD, is co-founder of Pacific Bioscience Laboratories, makers of the Clarisonic Sonic Skin Cleansing System and Opal Sonic Infusion System. He is responsible for the global expansion of the Clarisonic brand as well as new product development and international marketing. Prior to his new role, Dr. Robb served as Vice President of Clinical Research for Clarisonic. Dr. Robb received his PhD in Immunology from Texas A&M University and has spent over 25 years in medical and global health research.