

Preface



Cosmetic microbiology plays an essential role in product development, plant sanitation, product testing and research. We have come a long way since the 1960s when about 25% of marketed products were found to be contaminated with microorganisms. Now, only a handful of products released to the trade are found to be contaminated. Nevertheless, manufacturers continue to have microbiological issues with product preservation, house organisms, deionized water quality, and contaminated batches of product.

They say that “the devil is in the details,” and that is why the goal of this book is to address these details—to provide a discussion of various microbiological issues and arrive at insights—what I view as the proper way to deal with these issues based on more than 40 years of experience as an inspector and microbiologist with the US Food & Drug Administration, as a researcher with several major cosmetic companies, and as a microbiological consultant. It wouldn’t be fair for me to say that I’ve seen it all, because there is always something else that comes up, but I can say that I’ve seen a lot in the scores of manufacturing plants I have visited and in the discussions I have had with scientists and management in the cosmetic industry.

Within the pages of this book, the requirements of microbial growth and the principals of preservation are presented to give the reader an understanding of what is needed to control microbial growth—in the manufacturing plant, as well as in products. Microbial injury is discussed to let people know that metabolically-injured microorganisms may not be recovered from product samples using routine plating techniques and what may be done to recover these microorganisms during product release testing so they do not suddenly start appearing in shipped.

The keys to successful product preservation are presented to give the reader an understanding of what I feel is the right way to go about preservative efficacy testing so that products are adequately preserved—the first time and every time! When selecting preservative systems, one must consider the rate of killing of test organisms in the product, consumer use/abuse and the type of packaging, and understand it is essential to use the right acceptance criteria. The same considerations apply when designing preservative-free (i.e., self-preserving) products, as well as green/organic

products made from natural ingredients and atypical (i.e., low water activity/anhydrous) products.

No book on cosmetic microbiology would be complete without a discussion of preservatives. Preservatives are chemicals with antimicrobial action. Although they are needed to prevent unacceptable microbial growth in some formulations, their use has become controversial due to recent issues concerning their safety. Preservatives may be cytotoxic, cause skin irritation and contact sensitization. Additionally, some scientists are concerned about the ability of preservatives to modulate endocrine activity and to contribute to antibiotic resistance. The good news is that preservative levels may be reduced by taking advantage of synergisms, avoiding interferences with formula ingredients, and using hurdle technology. Some manufacturers are addressing this issue by eliminating the use of preservatives in products to have preservative-free (self-preserving) products based on the physicochemical composition of the formula and the use of multifunctional ingredients with antimicrobial activity.

Microbiological issues in the manufacturing plant present one of the most challenging areas for the microbiologist. Microbiological aspects of good manufacturing practices are discussed, and insights are provided for handling raw materials, deionized water, microbiological validation of processes, and cleaning and sanitization. House organisms are those microorganisms that have convinced manufacturers that they belong in the plant. This is not acceptable, so insights are given for dealing with “the bug in the plant”—to eliminate house organisms. With the current trend of outsourcing work, whether it is manufacturing or product testing, it is important to address microbiological issues for contract manufacturers and provide them with an action plan for maintaining microbiological control in their facilities.

When people in the cosmetic industry think about microbiology, they generally are thinking about plant sanitation or product contamination issues. However, there are other areas in which microbiology is very important. The normal microflora of human skin is comprised of resident, transient and infectious microflora. Many cosmetics and/or OTC drugs are intended to correct disorders caused or exacerbated by microorganisms. These products include cleansers, concealers, deodorants, acne treatments, and antidandruff, antiperspirant and antifungal products. Use of these products may modulate the microflora—by preventing their growth or killing them—to obtain the desired cosmetic benefit. Yet, studies with probiotics are showing us that the resident microflora may have beneficial effects, including prevention of infections by pathogens and down-regulating the

skin immune system, so it may be well to consider developing products that work with the normal microflora to maintain homeostasis and decrease the irritation potential of topical products.

Virtually everyone who has been involved with product development and testing has heard about *Pseudomonas* and the problems these bacteria cause. Pseudomonads are nutritionally versatile, adaptable and can grow in a variety of materials—from deionized water to complex formulas with preservatives. The reasons *Pseudomonas* is such a problem and insights for dealing with these bacteria are presented.

An entire chapter is devoted to discussing mistakes frequently made in product development and testing and how to avoid them. It's been my experience that it is better to design quality into a product than to try to fix problems after they occur. Recommendations are made for using preservative efficacy test acceptance criteria based on target test organisms, consumer use/abuse and packaging. Chemical testing for specific preservatives should not be substituted for actually conducting preservative efficacy tests because there are instances in which chemical tests show the proper preservative levels when the preservative efficacy tests fail because of interactions of preservatives with formula components or packaging. It is recommended that companies do not release products with viable microorganisms that may be able to grow in the product. The recurring theme in this book is to always opt for the more conservative approach when dealing with microorganisms because they will take advantage of us if given the chance—and the risks are too high to allow that to happen.

Cosmetic microbiology is alive and well, and will play an increasingly important role in the future. The issue of cross-resistance of formula ingredients with antibiotics needs to be resolved, and if there is a connection, appropriate screening/risk assessment procedures need to be put into place. There is a need for more reliable, rapid and inexpensive micro test methods. Many manufacturers need a better understanding of the micro issues in the manufacturing plant and how to resolve them. The globalization of markets requires the globalization of micro test methods and acceptance criteria so that issues with preservatives or testing do not interfere with product distribution and sales. We are just beginning to understand the cross talk between skin and its microflora. In the future, cosmetic microbiology will provide information needed to make products that are safer and more effective because they work in the body, as well as with skin microflora to improve the health and beauty of skin.

