
Cosmetic Safety

A Primer for
Cosmetic Scientists

edited by
James H. Whittam

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Cosmetic Safety

COSMETIC SCIENCE AND TECHNOLOGY SERIES

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- Volume 4: *Cosmetic Analysis: Selective Methods and Techniques*, *edited by P. Boré*
- Volume 5: *Cosmetic Safety: A Primer for Cosmetic Scientists*, *edited by James H. Whittam*

Other Volumes in Preparation

Introduction to the Series

The rapid growth of cosmetic science has made it virtually impossible for a single author or a single book to present a coherent review of the entire field. This series was conceived to permit discussions of a broad spectrum of current knowledge and theories of cosmetic science and technology. The series will be made up of books written either by a single author or by a number of contributors. Well-known authorities from industry, academia, and the government are participating.

The aim is to cover the many facets of cosmetic science and technology. Topics will be drawn from a wide spectrum of disciplines ranging from chemical, physical, analytical, and consumer evaluations to safety, efficacy, and regulatory questions. Organic, inorganic, physical, and polymer chemistry, emulsion technology, microbiology, dermatology, and so on, all play a role in cosmetic science. There is little commonality in the scientific methods, processes, or formulations required for the wide variety of cosmetics and toiletries manufactured. Products range from hair care, oral care, and skin care products to lipsticks, nail polishes, deodorants, powders, and aerosol products to over-the-counter drug products, such as antiperspirants, dandruff treatments, antimicrobial soaps, acne products, and suntan lotions. Thus, cosmetics represent a highly diversified field with many subsections of science and "art," for indeed today both art and instinct are used and needed in the formulation and evaluation of cosmetics.

Emphasis is placed on reporting the current status of cosmetic technology and science in addition to reviewing important historical concerns. The series will include books on safety, product testing,

preservatives, hair and hair care, oral hygiene products, aerosols, and claim substantiation. Contributions range from highly sophisticated and scientific treatises to primers, practical applications, and pragmatic presentations. Authors are encouraged to present their own concepts as well as established theories. They have been asked not to shy away from fields which are still in a state of development, nor to hesitate to present detailed discussions of their own work. Altogether, we intend to develop in this series a collection of critical surveys by noted experts covering most phases of the cosmetic business.

The fifth book in this series, *Cosmetic Safety: A Primer for Cosmetic Scientists*, edited by Dr. James H. Whittam, is designed as a guide to cosmetic formulators and students as a practical overview of the many and varied safety concerns involved in the development of cosmetics. The book is divided into two sections, Part I: General Safety Issues, and Part II: Safety Considerations in Specific Product Categories. It covers the full range of the industry's concerns and activities.

Cosmetic safety is a complex subject and allows for a multiplicity of scientific and philosophical approaches. New testing methodologies, questions on the use of test animals, more sophisticated and ever improving analytical techniques, and both scientific and political toxicity considerations are just a few examples of the currents that keep this field in constant flux. This book presents a view of the present state of the art in a field that continues to prove that nothing is as constant as change.

Finally, I want to thank all contributors and editors who are participating in this series, the editorial staff at Marcel Dekker, Inc., and above all, my wife, Eva, without whose editorial help and constant support I would never have undertaken this project.

Eric Jungermann, Ph.D.

Preface

It is becoming increasingly necessary for all individuals involved in the research, development, production, and distribution of cosmetic and personal care goods to have a better working understanding of the safety of their merchandise. It is stressed throughout this book that no general protocol or test can judge the safety of a product, but rather each product and product formulation must be judged on an individual basis. Nevertheless, the opinions and directions discussed here should provide effective guidelines and strategy to successfully evaluate product safety and decide on product integrity for the marketplace.

The chapters do not represent the protocols of the contributors' individual companies but rather guidelines and thoughts which should help both the beginner and the seasoned formulator in evaluating product safety.

Because of the complexity of the subject and the diverse opinions as well as changing legal and technical issues on safety, this text has been extremely long in development. I am deeply indebted to all the contributors for the hard work and long hours they spent in refining their approach. For all of us it has been a labor of love performed in the hope that we will help to promote a greater understanding of how to formulate, manufacture, and market safer products.

James H. Whittam, Ph.D.

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Introduction: An Overview of Product Safety

JAMES H. WHITTAM *Vidal Sassoon, Inc., Chatsworth, California*

I. COSMETICS—A CAPSULE VIEW OF THEIR HISTORY

Through the embellishment of artful cosmetics, our hair and skin become a canvas for display. Cosmetic fashion is one of the most enduring forms of personal expression.

From the strident war paint of tribal ritual to the delicate glimmering eye shadow of a modern woman, cosmetics have always aimed to intrigue the beholder and make the individual feel at his or her best.

Our complexions speak frankly of age and health. Since the dawn of civilization, cosmetics have been used to amplify or muffle the complexion's candor. In the name of vanity and ritual, our hair and skin have endured the endless alterations of cosmetics. Questions must then be asked: How safe are these beauty products? What practices are followed and concerns given in relation to cosmetic safety? The following chapter should provide some insights for the reader.

A. Cosmetics Through the Ages

Lipstick to shine the lips with color. Blusher for a rosy glow on the cheeks. Mascara and liner to dramatically darken eyes. These basic tools are part of almost every woman's cosmetic bag.

Throughout history women (and to a lesser extent men) had cosmetics that were intended to beautify them in the same way as modern cosmetics do today. However, without the sophisticated expertise of modern cosmetology, the crude cosmetics of olden days were often messy, smelly, and quickly turned rancid. Sometimes they were even poisonous, as in the case of lead-based white facial powder.

Four thousand years ago, ancient Egyptians were the first to use a pale foundation cream based on lead carbonate. Lips and cheeks were tinted with an orange-red shade. Eye shape was exaggerated with black kohl, a clay still used today by Bedouin women.

Roman women darkened their lips with red wine dregs and darkened their lashes with charred cork. They wore facial packs to bed that consisted of sheep fat and bread crumbs soaked in ewe's milk. These formulations smelled unpleasant and made Roman men very unhappy, ancient writers tell us.

Women in the Middle Ages used face creams made of whipped bear's brain, wolf blood, and crocodile glands. They shaved their eyebrows and made their face look pale with white lead powder.

But European women did not really begin to paint their faces in earnest until the Renaissance. Elizabeth I considered her looks a political asset and did not hesitate to use cosmetics to enhance them. Women everywhere imitated her and powdered their faces white and blushed their lips and cheeks with red ocher. A glaze of egg white preserved their made-up faces.

By the eighteenth century, both sexes wore makeup daily. A battery of creams and lotions was used for a luminous white complexion, while cheeks and lips were stained vermillion. Powder was still made of lead. As a result, people seldom looked youthful past the age of 30. Some died from lead poisoning.

False eyebrows were made of mouse skin, and cork balls were placed inside the mouth to make cheeks look stylishly plump. People also patched their faces with bits of silk and velvet cut into fanciful shapes to cover blemishes and disease scars.

The Pilgrims, and later the Victorians, cast a stern eye on such frivolities. Some cosmetics, such as soap, were still made in bubbling kitchen pots of lye and fat. But by World War I, women and cosmetics "came out of the kitchen" for good, and the cosmetics industry was launched.

B. Cosmetic Safety

Always eager to improve their appearance, people throughout time have been victimized by cosmetics that promised much but proved ineffective or unsafe.

—In the 1930s, American women used a coal tar-based eyelash dye. Many women used it without ill effect. For some, the dye caused an allergic reaction—dermatitis and itching around the eyes. But in 1933, two women suffered worse than that: One 52-year-old woman died. Another woman became blind in both eyes. After weeks of intense pain, the substance had eroded her corneas away. Her poignant testimony was used in congressional hearings that year on the need

for stronger food and drug laws. The case figured prominently in the debate on stronger regulations on cosmetics.

At the time, the U.S. Food and Drug Administration (FDA) had no legal authority to move against this product, because there was no provision in the law prohibiting the sale of cosmetics known to be harmful.

By 1938, Congress passed the Federal Food, Drug, and Cosmetic Act. The coal tar eyelash dye was the first product seized under its authority, approximately 5 years after the injuries were reported.

Cosmetics were now regulated to a degree, but much less so than drugs. The 1938 law mandated that cosmetics be safe. Later laws in 1966 and 1977 called for honest product ingredient labeling.

Today, data from the FDA as well as cosmetic manufacturers support the claim that cosmetics are some of the safest products on the market. In fact, today the FDA allocates only a small portion of its budget to inspect this multibillion dollar industry, in part because the industry effectively regulates itself. Modern reputable cosmetic companies thoroughly formulate, test, and retest products to make sure consumers are protected from harm.

C. Cosmetic Purity

In the last 50 years, cosmetology has truly made the leap from the alchemy of old to a modern chemical science in its own right.

Products have been consistently upgraded. Recent advances have incorporated the use of new ingredients in cosmetics along with improved methods to prevent spoilage and retard bacterial growth.

High standards of hygiene and microbiological safety guarantee that pure cosmetic products reach the consumer. Costly and exacting methods are used to sterilize manufacturing equipment and packaging materials for cosmetics.

Once the formulation is developed, cosmetic purity is assured in production by:

Thorough plant hygiene

Monitoring of raw materials to detect microbiological contamination

Assessing microbial status of finished products by careful statistical sampling

Long-term storage tests are routinely conducted on cosmetics.

These tests consist of exposing finished products, processed under normal manufacturing conditions, to a wide range of temperature, relative humidity, and atmospheric contamination. The products are then scientifically examined for deterioration and microbiological contamination.

Responsible cosmetic companies have long operated quality-controlled laboratories staffed with highly trained professionals to guarantee safety of cosmetic products. Today, cosmetics are better than ever.

D. Beauty Technology

Good hair and skin care depends on finding the most effective products and procedures—and avoiding those that are useless and harmful. This has become increasingly possible with the advances of highly sophisticated cosmetology. Modern cosmetic laboratories have come a long way from Egypt 1200 B.C.

The growing sophistication of cosmetic science has had a tremendous impact on the growth of the cosmetics industry in the twentieth century. Such innovations as liquid and compressed makeup, blushing gels, and mascara wands are all relatively recent.

Improved technology has vastly increased the range and combination of materials with which cosmetologists can work to formulate cosmetics. Laboratories can mix various materials to formulate new shades of color and fragrances. Through extensive testing, they can determine the safety and stability of new products. With computer data base systems, laboratories have access to more information than ever before. If cosmetic chemists want to study a new ingredient, they can get information from all over the world.

One of the biggest breakthroughs in the beauty field is the array of new laboratory instruments. They allow chemists to fine tune their formulations and provide the means for assuring reproducibility of product.

Classic tests on the effectiveness of beauty care products depended greatly on observations such as how did skin look or feel after a moisturizer was used. Now, there are instruments that provide quantitative data on skin smoothness, elasticity, moisture retention, and resilience. For the first time, the cosmetic scientist can measure how well a product works, in addition to consumer judgment (the ultimate test.)

Now more than ever, consumers can wear cosmetics and at the same time improve their skin quality. More thorough understanding of the biology of the skin permits the formulation of better skin protectors and minimization of skin irritants.

It was not until very recently, for example, that anyone knew how to get sunscreens into, say, a moisturizer, or improve damaged hair texture without losing cosmetic elegance. Cosmetic laboratories have now done both.

Although there is no such thing as a 100% nonallergic cosmetic, cosmetologists now can take steps to keep allergic reactions to a

minimum by thorough production methods, extensive testing, and elimination of any potential irritants. Physical, chemical, and biological compatibility of product ingredients are carefully tested for irritant effects on the skin and mucous membranes.

E. Who Regulates Cosmetic Safety?

As the entering student into the cosmetic industry will rightly see, regulation of the industry is a potpourri of key elements. The government clearly has put forth a policy known as the Food, Drug, and Cosmetic Act. However, because of the looseness of the original wording, we find that many cosmetic claims and product abuse fall under the Federal Trade Commission's jurisdiction on the basis of false advertising. With regard to safety, there are no set standards and procedures that are internationally accepted, such as one sees in more mature disciplines. In demonstrating safety and efficacy, corporations set their own protocol, and thus a major responsibility falls upon the various corporations to put forth a safe product. We can also say that the consumer very much regulates safety in an abstract sense, since adverse response to any product can often be the crucial factor in eliminating such a product and, often, the death of a company. A negative vocal public is not advantageous to any business, and thus sets forth its own demand that products be safe.

With regard to which legal agency of the U.S. government regulates cosmetic safety, the Food, Drug, and Cosmetic Act of 1938 defines "drug" and "cosmetic" and what the realms of their boundaries are. From a practical standpoint, however, the situation is not nearly so black and white. First, drugs and cosmetics cannot be separated on biological grounds when one is speaking about applying a product to our external appendages. Secondly, the general public today is much more educated; consumers read labels and want to know why and how a product works. Thus, treatment claims and claim substantiation data are very prevalent in the 1980s. Thirdly, as the science progresses, we find that what years ago we thought would remain only on the skin surface is now found to penetrate the skin into its many layers. Anything applied to or coming in contact with the skin, whether it be environmental air pollutants or just water, can influence the behavior and anatomy of the skin. As a result, endless debates among attorneys, dermatologists, and cosmetic scientists have created a gray area for the cosmetic product. The only thing that does clearly stand out is that the products, be they drugs or cosmetics, must be safe for public consumption and this, to a large extent, is left to the professionals responsible for developing and maintaining the products on the market today.