

Cosmetics Safety

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The safety of cosmetics recently has been called into question by consumer watchdog groups, and even the US federal government has looked into closer regulation of the cosmetics industry. These developments are interesting given the tremendous safety record of cosmetics manufacturers; nevertheless, it is worthwhile to examine cosmetics safety from a dermatologic standpoint, as physicians often are asked safety-related questions by patients (ie, Can cosmetics be used on diseased skin or while a patient is pregnant?).

It may be surprising that cosmetics are regulated, as the coloring agents that can be incorporated are strictly controlled by the Federal Food, Drug, and Cosmetic Act of 1938.¹ The only uncontrolled product category is soap. All other skin care products and cosmetics are covered by some regulatory document, but because there was concern that regulation would increase product cost and have detrimental effects on hygiene and infection control, the regulation of cleansers was not undertaken.

Control of the cosmetics industry began with the recognition that some products were tainted with lead, mercury, and arsenic. One of the most common bleaching creams (known as skin whitening cream at the time) was introduced in the 1930s and contained mercury; another similar cream contained arsenic. The introduction of these dangerous products led the federal government to recognize the need to protect consumers from these hazards. This type of protection is important, as the quickest way to lighten skin is to induce a state of anemia, which is how some skin whitening products worked!

This article will examine cosmetics safety from a historical perspective, looking at the development of cosmetics and current perceptions of safety. It is my hope that dermatologists will utilize this information to have a greater respect for the safety testing performed by all

large cosmetic companies to ensure proper performance of products and consumer safety.

The Earliest Cosmetics

The earliest cosmetics actually were not creams, liquids, or gels; they were cloth patches, known as beauty patches, designed to cover facial blemishes. These patches were developed in Europe in the 1600s to cover permanent facial scars on survivors of smallpox epidemics. The patches were made of black silk or velvet pieces in the shape of stars, moons, and hearts. Patch boxes, the forerunner of the mirrored facial compact, were carried everywhere to keep replacement patches handy should one fall off in public.² Wearing a beauty patch soon evolved into an unspoken language. For example, a patch near a woman's mouth suggested flirtatiousness, a patch on her right cheek indicated that she was married, and a patch at the corner of her eye signified smoldering passion.

A theatrical product known as French White was later developed.³ This cream was an improvement over loose powder that was dusted over the skin; it was used to whiten skin and cover scarring on the face, neck, and arms. It consisted of a white powder dissolved in a liquid vehicle that dried as a thin film over the body; however, it was easily removed with rubbing or sweating, thus discoloring clothing and making a mess. To increase the ability of cosmetics to stay on the skin with sweating, grease paints were developed with pigments and fillers suspended in oily vehicles for theatrical use. An adaptation of these early grease paints reached high popularity in the consumer market when Max Factor developed cake makeup, which was patented in 1936.⁴ Cake makeup provided excellent coverage, a velvety look, and facial color. Beginning with these early products, the consumer cosmetics category was born and has expanded tremendously over the last 75 years.

Eye Cosmetics Safety

The safety of eye cosmetics is an important consideration, as they frequently migrate or are accidentally introduced into the eye. Eyelid cosmetics have been used by both men and women since 4000 BC when green malachite powder

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was heavily applied to the upper and lower eyelids along with dark kohl eyeliner paste that was composed of powdered antimony, burnt almonds, black copper oxide, and brown clay ochre. Ground beetle shells often were added to produce glitter. The coloring agents that can now be used around the eyes are strictly regulated. No coal tar derivatives can be used; only approved purified natural colors or inorganic pigments as outlined in the Federal Food, Drug, and Cosmetic Act of 1938 are allowed.¹ The Table lists the coloring agents that are government approved for eye cosmetics.

The same types of restrictions also apply to eyelash cosmetics, more commonly known as mascara. Because coal tar-derived colors also are prohibited in mascara, colorants must be selected from vegetable colors or inorganic pigments and lakes. Color additives employed include iron oxide to produce black, ultramarine blue to create navy and umber (brown ochre), a mixture of hydrated ferric oxide with manganic oxide to produce burnt sienna, or synthetic brown oxide to create brown.⁶ It is important to note that only coloring agents are specified in the Federal Food, Drug, and Cosmetic Act of 1938, not preservatives or other ingredients, which encourages controversy regarding cosmetic regulation.

Lip Cosmetics Safety

The safety of the coloring agents used in lipsticks has received a great deal of attention due to the inevitable entry of lipsticks into the mouth. The US Food and Drug Administration divides certified colors into 3 groups: Food, Drug, and Cosmetic (FD&C); Drugs & Cosmetics (D&C); and External Drugs & Cosmetics (Ext D&C) colors. Only the first 2 groups can be used in lipsticks; Ext D&C colors can only be used in products that are intended for use in areas where they are not likely to enter the mouth.³

There has been some concern about the contamination of lipstick pigments with lead, which could be perceived as an issue on the surface but is actually a nonissue when investigated more deeply. The red pigments used in lipsticks may contain extremely minute amounts of lead but nowhere near the amount found in old paints, which has resulted in heavy metal poisoning if the lead dust was breathed or the lead-containing paint was eaten. The consumer would have to eat thousands of tubes of lipstick annually to achieve lead poisoning. As with everything, it is a matter of the degree to which something is used; an individual who eats large quantities of red lipstick should be careful.

Preservatives and Cosmetics Safety

Perhaps the biggest area of controversy surrounds the use of preservatives in cosmetics. Animals that are fed large

quantities of preservatives typically do not enjoy a long life, which is not surprising, as the primary role of antimicrobial preservatives is to destroy bacteria and prevent contamination; however, the risk of transferring infection from cosmetics contamination is much greater than the risk of applying minute amounts of preservative to the skin. Animal testing is performed through ingestion of the product to determine safety and carcinogenicity; because we do not drink facial foundation, ingesting preservatives is not an issue. Furthermore, the risk of contaminating cosmetics by sticking dirty fingers into the jar or transferring an ocular infection from one eye to the other via a mascara wand is much greater.

There has been a movement as of late to eliminate preservatives from cosmetics; however, it should be recognized that there is no such thing as a preservative free, commercially made cosmetic. Most cosmetics are not used for at least 3 to 6 months or more after they leave the manufacturing facility, which means some form of preservation is necessary. If the product does not contain water, fewer preservatives can be used because microbial growth requires water. Many products that are labeled as preservative free actually contain preservatives, but the ingredient falls under a different category. For example, phenoxyethanol has a lovely rose scent that may be used

Government-Approved Coloring Agents for Eye Cosmetics⁵

Aluminum powder, bronze powder, and copper powder
Annatto
Bismuth oxychloride
Caramel
Carmine
 β -Carotene
Chromium hydroxide green and chromium oxide greens
Ferric ammonium ferrocyanide and ferric ferrocyanide
Guanine
Iron oxides
Manganese violet
Mica
Titanium dioxide (alone or combined with mica)
Ultramarines
Zinc oxide

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as a fragrance, but it also is a preservative. Many spices, such as clove essences, can be used for a combination of fragrance and preservation. It also is possible to lower the preservative concentration with special packaging. Many of the newer facial foundations are dispensed in a jar affixed with a 1-way valve top that prevents oxygen and any outside agents from entering the jar.

In many ways, preservatives are a consumer's best friend, ensuring product stability and longevity until the jar is empty. On the label, ingredients are listed in order of descending concentration; preservatives usually are listed as the last 1 to 3 ingredients, signifying that preservatives are among the lowest ingredient concentrations. It is interesting to think that man fought over salt and spices to preserve food in the prerefrigeration era and now many groups are trying to restrict the preservation of cosmetics.

Safety Testing of Cosmetics

Why have there been so few instances of adverse events associated with the use of cosmetics? Because cosmetics are safe. Think of how many people use cosmetics on a daily basis and how few problems arise. Why are cosmetics so safe? Because large cosmetic manufacturers spend a tremendous amount of resources formulating safe products, searching for quality ingredients, designing packaging to maintain product purity, and writing labels that ensure the products are properly used by consumers. Most reputable manufacturers run safety tests on their products prior to marketplace introduction, which may include eye instillation, repeat insult patch testing, cumulative irritancy testing, and safety in use testing. Many companies also test their products on patients with sensitive skin, including those with a variety of dermatologic conditions such as eczema, rosacea, atopic dermatitis, and more.

Why are so many resources devoted to cosmetic testing? Because a product that causes problems in the marketplace tarnishes the reputation of the manufacturer and erodes consumer confidence, which means that every product the company manufactures is subject to question and can result in lost sales and lower revenues. No company wants to risk its reputation on a problematic product. It is perhaps the power of the consumer

marketplace that drives cosmetic safety, which is an inherent advantage of an open competitive marketplace.

Summary

This discussion begs one final question: Is it necessary to legislate additional cosmetics safety? For large international companies, additional safety legislation is unnecessary because there is not much more that can be enforced above and beyond the safety that is already built into each and every product. Safety of products that are purchased from third-world countries on the Internet may be problematic. However, would increased US legislation have an effect on promoting the safety of products purchased outside the United States over the Internet? No.

What should the dermatologist share with patients asking about cosmetic safety? First, the dermatologist should state that there is no magic cream to reverse aging that is available in a third-world country and is not sold in the United States. Simply put, do not buy cosmetics online from small manufacturers. Stick with nationally and internationally marketed brands. The best safety is built into products manufactured by companies who have a reputation at stake. Second, do not buy products that are compounded or do not come in commercial tamperproof packaging. No one can make a cosmetic that is any better than those commercially marketed. Third, do not purchase or use products that are questionable when traveling abroad. Look for recognizable brands.

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Quick Poll Question

Do you think the FDA should impose additional safety regulations on cosmetics?

Yes

No

Go to www.cosderm.com to answer our Quick Poll Question