

Makeup Wakeup Call

Companies that have eliminated phthalates are no doubt getting the message that people are paying more attention to ingredients. But public concern isn't the only factor driving the reformulations. Another reason is a European ban. Although the U.S. has outlawed just eight cosmetic ingredients, the European Union has banned more than 1,000. For companies that make cosmetics, complying with E.U. rules makes good business sense. It's more efficient to sell the same product worldwide. It's also good PR. About 380 U.S. companies have publicly pledged their allegiance to cosmetic safety by signing the Compact for Global Production of Safe Health & Beauty Products, under which they voluntarily pledged to reformulate globally to meet E.U. standards.

The reformulation trend is likely to gain further momentum from the California Safe Cosmetics Act of 2005, which took effect only this year. Manufacturers that sell over \$1 million a year in personal-care products in the state must report any products containing a chemical that is either a carcinogen or a reproductive or developmental toxic agent. Among those that must be disclosed are the phthalates DBP and di(2-ethylhexyl) phthalate (DEHP). California plans to make this information public, possibly on the Web, so some companies may choose to remove rather than report the ingredients.

Guinea pig nation

Despite the laws, pacts, and reformulations, questions about safety remain. Cosmetic industry critics argue that the Food and Drug Administration has not told companies what "safe" means, leaving them to make their own decisions. In fact, with cosmetics, the government generally takes action only after safety issues crop up.

Take the case of Rio hair relaxers. In December 1994, the FDA warned against two products sold through infomercials after consumers complained about hair loss, scalp irritation, and hair turning green. Rio announced that it would stop sales but there were reports that it continued to take orders. The California Department of Health then stepped in to halt sales and in January 1995, the U.S. Attorney's Office in Los Angeles filed a seizure action. By then, the FDA had received more than 3,000 complaints. Rio later reformulated and renamed its products.

The Rio case illustrates how holes in the government's cosmetic regulatory system can hurt consumers. The industry essentially regulates itself. The Cosmetic Ingredient Review panel, made up of physicians and toxicologists and funded by the industry's leading trade group--the Cosmetic, Toiletry, and Fragrance Association (CTFA)--assesses ingredient safety. Another industry group reviews fragrances and helps create safety standards. But manufacturers aren't obligated to do anything with this information.

"We're working on the honor system when it comes to cosmetics safety," says Jane Houlihan, vice president for research at the Environmental Working Group (EWG), a

Quick Read

Phthalates, a family of chemicals used in cosmetics, may pose significant health risks but:

- They're found in perfumes, nail polishes, and other products we use every day.
- Scientists say they're found in our bodies as well.
- In many cases, they're not listed on labels, so they can be difficult to avoid.
- Some manufacturers are removing them from their products, but the FDA has not restricted their use.

research and advocacy group. "In the absence of federal standards, we have a huge range of safety in the products we buy every day."

The FDA has made efforts to improve its ability to spot problems and issue warnings. The agency now has a computerized database, called CAERS, that collects reports of problems such as allergic reactions. Complaints can be sent via the FDA Web site or by calling a district office. But Amy Newburger, a dermatologist at St. Luke's-Roosevelt Hospital Center in New York City and a former member of the FDA's General and Plastic Surgery Devices Panel, says her experiences make her wonder about the system's effectiveness. In one case, she filed a report by phone and on the CAERS system after she and several of her patients got a rash with blisters after using an anti-aging treatment. It wasn't until a year later, in November 2006, that the FDA sent an e-mail asking her to complete some forms, she says. The FDA responds that it doesn't provide information or feedback to people who file complaints. It simply routes them to the appropriate office for evaluation. The FDA says it may also send reports to companies.

So what are the risks?

Scientists know very little about how repeated exposure to small amounts of phthalates in cosmetics may affect your health, if at all. But some studies suggest that the chemicals are present in our bodies.

In 2005, the federal Centers for Disease Control and Prevention reported that it had found breakdown chemicals from two of the most common cosmetic phthalates in almost every member of a group of 2,782 people it examined. A separate study published in the journal *Environmental Health Perspectives* (EHP) in 2005 showed that men who used the most personal-care products, such as after-shave and cologne, had the highest urinary levels of a breakdown product of diethyl phthalate (DEP).

In rodent studies, phthalates have caused testicular injury, liver injury, and liver cancer. We found no such clear hazards in human research. But we did find studies suggesting that phthalates may be associated with other health issues, including the following four examples from one source alone, EHP, which is a leading journal published by the National Institutes of Health. In 2000, EHP published a small study that said elevated blood levels of phthalates were associated with premature breast development in young girls. Another report in 2003 found that men with higher concentrations of two phthalate breakdown products in their urine were more likely to have a low sperm count or low sperm motility. A study published in 2005 said women with higher levels of four phthalate compounds in their urine during pregnancy were likelier to give birth to boys with smaller scrotums. And a 2006 report cited low testosterone levels in male newborns exposed to higher levels of phthalates in breast milk.

Experts in the industry and the government are aware of such reports but say there is no cause for alarm. The FDA, for instance, concluded after a thorough review of the literature that "it's not clear what effect, if any, phthalates have on health." And the CTFA, the industry trade group, notes that government and scientific bodies in the U.S. and Canada have examined phthalates without restricting their use in cosmetics. After the 2005 report linking phthalate exposure to smaller scrotum size, in particular, the trade group said, "The sensational and alarming conclusions being drawn from this single study are completely speculative and scientifically unwarranted."

Even companies that have dropped phthalates from products say they are safe. "This policy is driven by a wish to allay public concern and does not reflect concern with the safe use of the ingredients," Avon said after announcing that it would cut DBP from its product line. John Bailey, the CTFA's executive vice president for science, says ingredients like DBP in nail polish are simply not a hazard in such small amounts.

On the other side are some environmental and public-health advocates who say possible carcinogens and reproductive toxins do not belong in cosmetics, no matter how small the amount. "We take issue with the idea that a little bit of poison doesn't matter, because safer alternatives are available," says Stacy Malkan, communications director of Health Care Without Harm. "Companies should be making the safest products possible, instead of trying to convince us that a little bit of toxic chemicals are OK." While the scientific jury is still out, we at ShopSmart believe it makes sense to reduce your exposure to phthalates, especially if you're nursing, pregnant, or trying to become pregnant.