Parabens, Carcinogens and Certified Organic Ingredients

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Q. After reading about a British study reporting that parabens in antiperspirants contribute to breast cancer, some of my clients don't want the substance in their cosmetics. I am looking to you to help clarify this issue for me. Are parabens harmful, or are they safe? Is it true that they have been banned in Europe and Japan?

A . Parabens, which are widely used antimicrobial preservatives for cosmetics, are among the most studied of all cosmetic ingredients and have a long history of safety. Although there is an Internet myth claiming that they have been banned in both Europe and Japan, it is not true. Parabens are allowed for use by every government agency that regulates cosmetics worldwide.

Used since the 1920s in thousands of cosmetics and pharmaceuticals, as well as in a few foods, parabens are a family of chemicals known as alkyl esters of p-hydroxybenzoic acid. They have various prefixes that refer to the length of the alkyl ester group that branches off of the acid. These include methyl, ethyl, benzyl, propyl and butyl.

Methylparaben is the shortest chain—or smallest molecule—of the group, butylparaben is the longest and the others are of various midlengths. Several parabens are found in nature, including methylparaben. This most popular variety is produced by certain mold species in order to protect themselves from hostile bacteria. However, to my knowledge, none that are used in cosmetics or other commercial products come from natural sources. All of those utilized in cosmetics are derived from petroleum.

Throughout the past decade, parabens have been recognized as several of the more than 8,000 endocrine disrupters (EDs) in the environment. These chemicals, which behave like animal estrogens, can affect hormone balances adversely or disrupt the normal function of organs that are controlled by hormones. Among the more popular plant EDs are phytoestrogens, which are found in soy, hops, Angelica sinensis (dong quai), Salvia officianalis (sage), clary sage, red clover, pumpkin, poppy, St. John's wort, rosehips, yarrow and some seaweeds. They now are believed by many researchers to contribute to the increasing incidences of breast cancer, low sperm count and other estrogen-influenced medical problems in humans, as well as to alter the sexual characteristics of fish, frogs and other species by contaminating fresh water supplies.

Although parabens are 1,000–1,000,000 times weaker than natural estrogenic compounds, with methylparaben being the weakest of the group, phytoestrogens are approximately 400 times weaker than human estrogen. But, due to the fact that parabens appear to be used more commonly in cosmetics and foods, and because they are produced synthetically from petroleum, some researchers are more worried about their estrogenic effects but show little alarm about the natural phytoestrogens found in cosmetics and foods.

Because parabens are known to penetrate the skin, concern has been voiced by some researchers and consumer watchdog organizations that those that are included in cosmetics might act as EDs when applied to the skin. Cosmetic chemists who are familiar with the skin-penetration activity of parabens maintain that this is not possible because, once they enter the skin, they form metabolites that are incapable of mimicking estrogen.

At the beginning of 2004, a study was published by an English toxicologist that seems to put this accepted scientific knowledge into doubt1. Phillipa Darbe, PhD, a senior cancer researcher at the University of Reading in the United Kingdom, reportedly stopped using antiperspirants in the mid-1990s, due to a gut feeling that they were connected to breast cancer. Seven years later, she looked for the presence of parabens—ingredients she believed were usedin deodorants and antiperspirants—in 20 breast tumors and found them in 18. Although stopping short of stating that the parabens came from underarm products, she did claim that the chemical form of those she discovered indicated that they had been applied to the skin, rather than consumed. She advised that further research be completed in order to determine their source.

Unfortunately, Darbe's findings have been misreported widely by news agencies, cosmetic companies and others as proving that parabens cause breast cancer, with the likely contributors being antiperspirants and deodorants. Some reports even state that the Darbe study shows a clear connection between these products and breast cancer.

In January 2005, the European Union's Scientific Committee on Consumer Products (SCCP) published an opinion paper that evaluated paraben safety in relation to breast cancer2. Shortcomings in the Darbe study are among its findings. These include the following.

• A lack of control tissue against which to measure paraben levels in other areas of the body or in breasts that did not contain tumors.

• No report of the subjects' therapeutic history, which may have uncovered other sources of paraben exposure.

• No mention of the paraben-containing anti-cancer drugs that the tumor subjects were using.

• No report of the subjects' exposure to consumer products containing parabens.

• No description of how the tissue was handled. Contamination could have occurred then.

The SCCP report also notes that methylparaben was the most frequently occurring paraben found in the breast tumors, yet it contains the lowest estrogenic activity. The strongest estrogen mimic—butylparaben—was the least represented, probably due to its larger molecular size. And, although Darbe suggests that the paraben source may be underarm cosmetics, the SCCP states that 98% of underarm products, including deodorants and antiperspirants, do not contain them. Therefore, it is highly doubtful that the substance could have come from these products.

The SCCP concluded that "There is no evidence of demonstrable risk for the development of breast cancer caused by paraben-containing underarm cosmetics," especially in view of the weak estrogenic potential of these ingredients. "With regard to their general toxicological profile, acute, subacute and chronic toxicity studies in rats, dogs and mice have proven parabens to be practically nontoxic, not carcinogenic, not genotoxic or co-carcinogenic, and not teratogenic (i.e. fetal toxicants)."

Although the safety of parabens that are applied to the skin is practically conclusive, their effects, along with those of other EDs in the environment, remain a concern. However, removing them from cosmetics will do little good if the rest of the 8,000 EDs in the environment are not decreased.

Q. I recently heard that California now has a law that prohibits the use of carcinogens in cosmetics. Is this true?

A . No. The law you are referring to—the California Safe Cosmetics Act of 2005—does not prohibit the use of any ingredients in cosmetics. Instead, it requires cosmetic manufacturers and brands with total company sales of $1,000,000 or more to report those products that include chemical ingredients identified by the state's Department of Health Services (DHS) as known or suspected carcinogens or fetal toxicants to the organization. In addition, cosmetic companies must report fragrance and flavor compounds that are on the same list of chemicals. The bill apparently applies to ingredients that appear ona product's ingredients list, but not to the residual elements of those ingredients.

Although the list of toxicant ingredients has not been finalized as of press time, insiders believe that the act will recognize the more than 750 substances that are identified in the state's Proposition 65 regulation—officially known as the Safe Drinking Water and Toxic Enforcement Act of 1986. This list can be viewed at www.oehha.ca.gov/prop65.html.

Although Proposition 65 requires a manufacturer to post consumer warnings when a product contains harmful levels of one or more of the identified substances known by the state to cause cancer, birth defects or other reproductive harm at the point of sale, the California Safe Cosmetics Act of 2005 goes further by requiring companies to inform the state if a product contains any level of the substance.

Rationale for the new legislation is based on the concept that individuals can use multiple products containing carcinogens or fetal toxicants, thereby causing levels of exposure to exceed safe limits that are not taken into account with Proposition 65. What is not considered is that the allowable levels noted in Proposition 65—no significant risk levels (NSRLs) for carcinogens and maximum allowable dose levels (MADLs) for fetal toxicants—are based on maximized exposures that are known as "safe harbor levels."

The safe harbor NSRL for carcinogens is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming each person is exposed to the level in question for 70 years. The safe harbor MADL is the level at which the chemical in question would have no observable adverse reproductive effect at 1,000 times the level of allowed exposure.

To put this into perspective, let us examine one of the ingredients that most likely will be added to the Proposition 65 list next year—dibutylphthalate. This is a substance that is mixed into nail polish to help it spread more easily. Banned in the European Union due to its effects on animal fetuses, it has a margin of safety that is 36,000 times the amount usually used in nail polish. In other words, you could eat15 bottles of nail polish a day for seven years and still not get the effect noted in animal tests.

Compare that to another fetal toxicant—theobromine. A component of chocolate, this chemical is so strong that you could divide a chocolate bar, which contains one of the weakest levels of commercially sold theobromine, into 1,700 pieces, eat one piece a day and receive the same level of reproductive toxin exposure as the dibutylphthalate in nail polish. Currently, there is no legislation proposed in California to regulate theobromine exposure in chocolate.

Q. Is it true that cosmetics now can be certified organic in the same way that foods can?

A . Following a heated campaign that included official complaints and a lawsuit lodged against the United States Department of Agriculture (USDA) by cosmetic companies and consumer groups, including the Organic Consumers Association, the USDA's National Organic Program (NOP) recently recognized those cosmetics and cosmetic ingredients that meet the agency's standard as eligible for organic certification.

In a memo published on this subject on August 24, 2005, the USDA stated, "There are agricultural products, including personal care products, that, by virtue of their organic agricultural product content, may meet the NOP standards and be labeled as '100% organic,' 'organic' or 'made with organic,' pursuant to the NOP regulations."3 Prior to the issuance of this statement, companies could receive organic certification for such agriculturally produced ingredients as plant extracts, but the finished product was not eligible.

However, unlike foods, cosmetics that do not conform to the NOP's organic standard still can feature the word "organic" in their product or company name, and companies may use it to describe the product itself. This is because the U.S. Food and Drug Administration (FDA), which is the main government agency that regulates cosmetics, maintains a position that "organic" is an unregulated marketing claim. For more information about organic as it applies to cosmetics, refer to this column in the September 2003 issue of Skin Inc. magazine.

FOOTNOTES

1 Darbe et al, Concentrations of Parabens in Human Breast Tumors. Journal of Applied Toxicology (24), 5 (2004).

2 SCCP Opinion on Parabens, Underarm Cosmetics and Breast Cancer (January 28, 2005).

3 www.ams.usda.gov/nop/NOP/NOPhome.html.