



Final Thought

Cosmetics have a long history of safe use by millions of people, and most of the recent claims of health hazards are overstated or unfounded. The cosmetic industry bears the main responsibility for the safety of its products. The results of safety tests are not always publicly available. Cosmetic manufacturers have internal processes and testing protocols designed to ensure the safety of the products they manufacture. In addition, the FDA oversees ingredient safety and has the ability to remove unsafe products from the market, and the CIR conducts ingredient testing and advises the industry on ingredient safety matters. Very few incidents of injury or illness from cosmetics have ever been reported, and most of these involve irritation or mechanical injury (such as scratching the eye with a mascara wand).



No data exist linking cosmetics with cancer, reproductive effects, or genetic damage in humans. Much of the anxiety surrounding the health "hazards" of cosmetics stems from misperception regarding how safety testing is done. High-dose tests performed on laboratory animals, especially rodents, are often misinterpreted when it comes to predictions about human health hazards, particularly since cosmetics usually only contain trace levels of the chemicals of concern. ♦

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## The Health Claims Against Cosmetics

Cosmetics are health and beauty products such as toothpaste, antiperspirant, lipstick, eyeliner, and hand lotion. Many of us have used one or more of these products every day for many years without giving them a second thought. Recently, some activist groups have claimed that cosmetics pose dangers to our health, and may even be cancer-causing. Since these products are very common, it is important to evaluate the scientific accuracy of these claims. So, before you empty your medicine cabinet of all of that supposedly lethal lipstick, deadly deodorant, and toxic toothpaste, take a moment to consider the facts about cosmetics.

### Do Cosmetics Cause Cancer?

Sometimes the health claims against cosmetics seem convincing because they cite studies showing the toxic effects of certain products on animals. While animal testing is a useful scientific tool in some respects, it is important to realize that these tests are often carried out in such a way that limits their relevance to human health.

It is important to remember that with any chemical, "the dose makes the poison." In other words, chemicals may be associated with tumor development when tested on laboratory animals at very high doses but not when administered at more commonplace levels. Tests carried out on laboratory animals often involve administering very high doses of chemicals over long periods of time. The doses that humans are actually exposed to when using cosmetics are dramatically lower. Furthermore, humans may only be exposed to the chemical in question in a diluted form. For example, a lab test may expose animals to a 100% pure product despite a typical cosmetic product only containing that chemical in a 5% ratio. Finally, the route of exposure in laboratory tests often does not match the way in which cosmetics are actually used. With the possible exception of lipstick, cosmetics are not routinely ingested. Therefore, to cite studies that show toxic effects in laboratory animals that were subjected to oral exposure is misleading. There is no sound scientific evidence that cosmetics as they are typically used cause cancer.

*The Bottom Line: Animal tests alone are not necessarily reliable evidence of risk. There is no evidence that cosmetics as typically used cause cancer in humans.*



## Who's Making Sure Cosmetics Are Safe?

Some activist groups have complained that the industry is largely self-policing. This is true to some degree, as the Federal government does not subject cosmetics to the same premarket approval process that it uses for pharmaceutical products. This does not mean, however, that cosmetics are not carefully tested and regulated. The industry itself has an interest in rigorously testing chemicals on its own before marketing them — safety testing is essential if a company wants to conduct business in the U.S. without the burden of product recalls, consumer complaints, and lawsuits. By law, any cosmetic that has not been adequately tested prior to marketing must bear the label "Warning: The safety of this product has not been determined." If a product does not have such a label, this indicates that the company has evaluated the product and certifies its safety.

In addition, the U.S. Food and Drug Administration (FDA) plays a significant role in ensuring cosmetic safety. The FDA has the authority to ban or restrict ingredients in cosmetics. If the agency is concerned about the safety of a product, it has the power to mandate warning labels on products, issue warning letters to cosmetic companies, and work with manufacturers to implement nationwide product recalls if necessary. The FDA has the ability to inspect cosmetic manufacturing facilities, to seize illegal products, and to prosecute violators of safety laws. The Federal Food, Drug, and Cosmetic Act prohibits the marketing of adulterated cosmetic products, placing the burden of safety directly on the cosmetic industry.

The Cosmetic Ingredient Review Board (CIR) provides another important mechanism for ensuring the safety of cosmetics. The CIR is an independent scientific body consisting of scientists who have been nominated by consumer, scientific, medical, governmental, and industry groups. Although the CIR receives funding from the Cosmetic, Toiletry, and Fragrance Association, it maintains total editorial and voting independence from this group. The CIR assesses the ingredients used in cosmetics, publishes its results in a peer-reviewed scientific journal, and makes recommendations to cosmetics manufacturers.

*The Bottom Line: The FDA oversees cosmetic safety and has the power to remove unsafe products. The CIR tests and evaluates ingredients, and it is in the best interest of the industry to follow their recommendations.*

## How Are Cosmetics Tested for Safety?

When a new product is being developed, scientists conduct an extensive review of the scientific studies that have already been published on its ingredients. When the existing literature does not provide adequate information about a product's safety, researchers may want to proceed with laboratory studies, either on humans, on animals, or in test tubes. Experiments that use skin as the primary route of exposure are the most helpful, since this is the most common way in which humans come into contact with cosmetic products. These tests determine both whether a product will cause irritation and its ability to move through the skin. It is also important to test the effects of one-time oral exposure, however, in case of accidental ingestion of the product.

Studies on cosmetic ingredients are performed with several goals in mind. Scientists attempt to identify any potential hazards of the product, including effects on the reproductive and respiratory systems, effects of the product on the eyes in case of accidental splash, and potential to cause cancer with long-term exposure. By identifying possible hazards, scientists can make a risk assessment for the product, which typically includes an extra margin of safety to protect against unexpected adverse effects.

*The Bottom Line: Cosmetics undergo several types of safety testing before entering the market.*



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## Specific Concerns: Phthalates and Parabens

Specific claims have been made against two classes of chemicals used in cosmetics: phthalates and parabens.

**Phthalates**, including dibutyl phthalate (DBP) and diethyl hexyl phthalate (DEHP): It has been suggested that phthalates may cause breast cancer, birth defects, and harm to the reproductive system. The International Agency for Research on Cancer (IARC), however, concluded that rat tumor data and long-term studies in animals measuring the effects of DEHP are probably of little relevance to humans because of the large differences in the way that rats and humans process chemicals. A recent study in a monkey species — which is much closer to humans in body structure and function than rodents — indicated that the monkeys were much less sensitive to DEHP exposure than rats. Similarly, the Center for the Evaluation of Risks to Human Reproduction, part of the National Institutes of Health's Toxicology Program, concluded in 2000 that "it has minimal concern about effects to human development and development of the reproductive system from current estimated exposure to DBP." The FDA agrees that there is no evidence that phthalates as they are used in cosmetics pose any safety risks. There is no compelling data to suggest that phthalates in cosmetics cause any kind of human cancer, including breast cancer.

**Parabens**: Some activist groups have expressed concern that parabens in cosmetics will mimic estrogen in the body. Specific concerns include the risk of breast cancer from parabens' estrogen-like effects. In fact, laboratory tests have shown that the actions of paraben are 1,000 to 1,000,000 times weaker than natural estrogen. Parabens do not accumulate in human tissue over time. Two recent studies could not establish a link between the use of underarm deodorants and breast cancer. Parabens have a long history of safe use and have been specifically recognized as safe by the FDA. The CIR reviewed the use of parabens in cosmetics in 1984 and concluded that they did not pose a risk to consumers. Several re-reviews since that time have come to the same conclusion.

*The Bottom Line: The FDA and the CIR agree that there is no evidence that either phthalates or parabens in cosmetics pose a health threat.*

