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## Cosmetics

Ingredients used to make consumer products (including cosmetics) have come under increased scrutiny for their possible effects on human health and on the environment. This is in part fueled by the increase in information on the Internet about the chemicals in consumer products, including cosmetics.

This document is a brief overview of cosmetics, how they are regulated, and what is (and is not) known about their possible health effects, as part of the American Cancer Society's role in informing and educating people about cancer and its possible causes. The American Cancer Society does not maintain lists of the chemicals used in cosmetics or have position statements about specific ingredients or products. A list of websites addressing these issues is provided later in this document.

### What are cosmetics?

According to the US Food and Drug Administration (FDA), the law defines cosmetics as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body... for cleansing, beautifying, promoting attractiveness, or altering the appearance." This includes skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, shampoos, permanent waves, hair colors, toothpastes, and deodorants, as well as any component of a cosmetic product. It does not include products used solely as soaps.

Cosmetics are different from drugs, which are defined as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals."

This difference is important when it comes to federal oversight of these products, which is described in the section "How are cosmetics regulated?"

## Do cosmetics cause health problems?

Cosmetics include a wide range of products. Some of these can cause health problems in some people, such as skin or eye irritation or allergic reactions. These types of problems are usually short-term and go away if use of the product is stopped.

Whether cosmetics or certain ingredients in them cause more subtle or long-term health problems is not entirely clear. Uncertainty exists because many products and ingredients have not been tested thoroughly. Even when ingredients in cosmetics have been tested, the results may not always be simple or clear cut. For example, some ingredients in cosmetics have been found to be toxic in large amounts (or at high concentrations). But the amounts of these ingredients used in cosmetics is typically much lower than what caused ill effects in studies. Plus the way the ingredient is used in a cosmetic may be different from how it was used in the tests. Also, there is often little information about what ingredients are absorbed into the body (and how much they are absorbed) when applied to the skin during actual product use. For these reasons, the ingredient may not cause the same problems in actual use in a cosmetic.

Because human studies of the long-term effects of most cosmetics (except, perhaps, [hair dyes<sup>1</sup>](#)) don't exist, there is little evidence to suggest that using cosmetics, or being exposed to the ingredients in cosmetics during normal use of these products, increases cancer risk. Still, because there are no long-term studies, little is known about the health effects of long term exposure to many ingredients in cosmetics. This means that we cannot claim that these products will not cause health problems in some people.

## How can products be tested for safety?

The ingredients in cosmetics are routinely tested for short-term health problems such as skin and eye irritation and allergic reactions. But the actual cosmetics themselves (specific lipsticks, eye shadow, etc.) are seldom tested for short-term health effects. Because of this, it may not be known if the ingredients when combined together cause problems that were not seen when they were studied individually.

Very little information is available on long-term health impacts of most cosmetic ingredients or cosmetic products. It is difficult to test the ingredients in cosmetics for harmful long-term health problems such as cancer. For most substances that cause cancer, it takes many years after exposure to the substance for cancer to occur. That means the studies would need to go on for at least 10 or 20 years to see if a certain substance or cosmetic caused cancer. It is also not practical to test every combination and dose of these ingredients in the actual cosmetic products. This is made especially difficult by the fact that ingredients (and combinations) change frequently. That means

looking at the risk from a certain cosmetic (for example a lipstick) over time would be complicated by the fact that, even if the people in the study kept using the same product over many years, the product itself would likely change.

Therefore, scientists must resort to other types of tests – typically of only 1 or 2 ingredients at a time and at much higher doses and through different routes of exposure than people would normally have through typical use of cosmetics– to try to determine the potential of a chemical to cause cancer.

## **Lab studies**

Scientists get much of their data about whether something might cause cancer from lab studies using cell cultures and animals. Because there are far too many substances (natural and man-made) to test each one in lab animals, scientists use knowledge about chemical structure, other types of lab tests, and other factors to select chemicals for testing. They can often get an idea about whether a substance might cause problems by looking at its chemical structure and comparing it to similar chemicals.

Virtually all substances known to cause cancer in humans also cause cancer in lab animals. But the reverse is not always true – not every substance that causes cancer in lab animals causes cancer in people. There are different reasons for this.

First, most lab studies of potential carcinogens (cancer-causing substances) expose animals to doses that are much higher than common human exposures. This is so that cancer risk can be detected in relatively small groups of animals. But doses are very important when talking about toxicity. For example, taking a couple of aspirin may help with your headache, but taking a whole bottle could put you in serious trouble. It's not always clear that the effects seen with very high doses of a substance would also be seen with much lower doses.

Second, there may be other differences between the way substances are tested in the lab and the way they would be used, such as the route of exposure. For example, applying a substance to the skin is likely to result in much less absorption of the substance into the body than would be seen if the same substance is swallowed, inhaled, or injected into the blood. The duration and dose of the exposure also help determine the degree of risk.

Finally, the bodies of lab animals and humans don't always process substances in the same way, so a substance that may cause harm to one may not have the same effect on the other. As an example of this type of difference, you may like chocolate, but you probably know that it could make your dog very sick.

Most of the ingredients in cosmetics that have been tested in animals for long-term health effects were studied in ways that apply more towards the effects of higher dose exposures that may be seen in workplace settings. It isn't always clear how the results of these studies apply towards exposure to the same substances in cosmetics.

Despite these limitations, laboratory studies are the best way to detect the potential for a substance to cause cancer in humans before widespread exposure occurs.

### **Epidemiologic (population-based) studies**

Epidemiologic studies look at human populations to determine which factors might be linked to cancer. These studies provide useful information, but they also have their limitations. Humans do not live in a controlled environment. People are exposed to many substances at any one time, including those at work, school, or home; in the food they eat; and in the air they breathe. It's very unlikely people truly know exactly what they've been exposed to or that they would be able to remember all of their exposures if asked by a researcher. And it is usually many years (often decades) between exposure to a carcinogen and the development of cancer. Therefore, it can be very hard to single out any particular exposure as having a definite link to cancer.

By combining data from both lab-based and epidemiologic studies, scientists do their best to make an educated assessment of a substance's cancer-causing ability. But often there simply isn't enough information to be certain one way or the other. Most experts believe that substances which cause cancer in animals should be treated with caution because they have the potential to cause cancer in humans.

Federal and international agencies who try to determine if a substance causes cancer typically classify an exposure as being either a *known* human carcinogen, *probably* carcinogenic to humans, or *possibly* carcinogenic to humans. Not surprisingly, most chemicals that make these lists fall into the possibly carcinogenic category, meaning there is potential for cancer but no evidence or only limited evidence of this in humans. Most often, this means that no epidemiologic studies have been done or those that have been done have serious limitations. (For more information on how different agencies classify potential carcinogens, see [Known and Probable Human Carcinogens<sup>2</sup>](#).)

### **How are cosmetics regulated?**

In the United States, both cosmetics and drugs are regulated by the FDA. For drugs, the FDA requires that new products be shown to be safe and effective before they are allowed to be sold. This is not the case for cosmetics. Although the FDA requires that cosmetics be safe, it does not have the authority to require companies to test their

cosmetic products (except some color additives) before they are put on the market. The FDA holds cosmetic firms responsible for confirming the safety of their products and ingredients prior to marketing. Products that have not been tested must carry the label, "Warning -- The safety of this product has not been determined."

Most testing of cosmetics (and their ingredients) look for short-term effects such as skin or eye irritation or allergic reactions. Short-term health effects are likely to become apparent once a product reaches the market and is used widely. It is much more difficult, however, to identify long-term toxic or carcinogenic (cancer-causing) effects.

Cosmetics intended for retail sale must have a list of ingredients on the label. The list does not have to include flavor, fragrance, or trade secret ingredients. Products for use by professionals and samples distributed free of charge are not required to list ingredients on their labels.

The FDA can take action if it has reliable information that a product on the market is not safe. It can:

- Ask a federal court to issue an injunction
- Request that US marshals seize the products
- Initiate criminal action
- Refuse entry of an imported cosmetic

Although it cannot require recalls of a product, it can request that a company recall a product.

In California, a law called the California Safe Cosmetics Act requires companies to report cosmetics products sold within that state that contain ingredients known or suspected to cause cancer, birth defects, or other reproductive harm. This information is reported to the California Safe Cosmetics Program, which maintains a searchable database of cosmetics sold within the state.

## **Same data, different views**

Information about cosmetics is often presented with widely divergent points of view with respect to the potential for health problems.

## **Innocent until proven guilty?**

There are those who believe that the products are adequately regulated, and that

because they haven't been shown to cause problems they should be considered completely safe. The weakness of this argument is that there are many gaps in the evidence, particularly on the extent to which the ingredients in cosmetics can be absorbed and build up in the body. Further, just because a substance hasn't been shown to cause a problem doesn't ensure that it is risk-free.

Most scientists and regulatory agencies believe that it is very unlikely that cosmetic ingredients have serious health effects because of the low dose from such exposures, even with regular use. The assumption that the doses are low is generally based on the low levels of specific substances in cosmetic products, the limited areas of the body where they are used, as well as limited absorption through the skin. However, these assumptions are not always correct. For example, benzophenone-3, an ingredient in some sunscreens, can be measured in urine samples from most people in the United States.

### **Better safe than sorry?**

There also are people who believe that *any* evidence that a substance may be linked to cancer, regardless of the dose or route of exposure, should cause it to be banned from use, if possible. This is the perspective taken by some advocacy groups such as the Campaign for Safe Cosmetics.

Particularly controversial are chemicals considered to be "endocrine disruptors," which can mimic the natural hormone estrogen. When made by the body or given as a drug, estrogen affects reproductive organs and can raise the risk of certain cancers. There is a good deal of controversy about the effects of much lower exposures to chemicals that mimic estrogen in the body. Some groups have called for banning all such substances. This is complicated, because certain foods such as tofu and soy milk contain these compounds naturally.

### **More data are needed**

The American Cancer Society takes seriously its role as a provider of trusted, credible information on issues related to cancer. Such information is essential for individuals and regulatory agencies to make informed decisions about the safety of consumer products. More information is needed on the extent to which the ingredients in cosmetics are absorbed and retained in the body during normal usage, especially in groups who may be especially vulnerable to ill effects, such as infants, pregnant women, and the elderly. Furthermore, the American Cancer Society supports the need for open and transparent regulatory oversight of cosmetics and encourages continued and expanded scientific research on the potential links between cosmetic use and cancer risk. The need for an

effective FDA in ensuring the safety of our food supply, medicines, and consumer products has never been greater.

In the meantime, people who are concerned about the possible health effects of cosmetics may wish to visit the websites listed below to learn more about the products and what may be in them. Concerned individuals may choose to avoid certain products or to minimize or avoid cosmetic use altogether. Consumers should be aware that there is no evidence that cosmetic products labeled as "natural," "organic," or "green" are in fact safer than products that do not carry these labels.

The American Cancer Society continues to support the use of sunscreen products as one of the measures to limit skin exposure to [ultraviolet radiation](#)<sup>3</sup>, while encouraging continued research on the safety and efficacy of these products.

## Hyperlinks

1. [www.cancer.org/cancer/cancer-causes/hair-dyes.html](http://www.cancer.org/cancer/cancer-causes/hair-dyes.html)
2. [www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html](http://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html)
3. [www.cancer.org/cancer/cancer-causes/radiation-exposure/uv-radiation.html](http://www.cancer.org/cancer/cancer-causes/radiation-exposure/uv-radiation.html)
4. <http://www.fda.gov/>
5. <http://www.fda.gov/cosmetics/default.htm>
6. <http://www.cosmeticsinfo.org/>
7. <http://www.cosmeticsdatabase.com>
8. [www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/CSCP/Pages/CSCP.aspx](http://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/CSCP/Pages/CSCP.aspx)

## Additional resources

In addition to the American Cancer Society, other sources of information include\*:

**Food and Drug Administration (FDA)** Website: [www.fda.gov](http://www.fda.gov/) (<http://www.fda.gov/>)<sup>4</sup>  
Cosmetics page: [www.fda.gov/cosmetics/default.htm](http://www.fda.gov/cosmetics/default.htm)  
(<http://www.fda.gov/cosmetics/default.htm>)<sup>5</sup>

- This site contains information on cosmetics from the Food and Drug Administration, the federal agency responsible for overseeing cosmetics in the United States.

**Cosmeticsinfo.org** Website: [www.cosmeticsinfo.org](http://www.cosmeticsinfo.org/) (<http://www.cosmeticsinfo.org/>)<sup>6</sup>

- This site, run by the Personal Care Products Council (a trade association representing the cosmetics, toiletry, and fragrance industry), contains information about the safety, testing, and regulation of cosmetics and personal care products and their ingredients. It contains safety information pages and an ingredient database.

**Skin Deep** Website: [www.cosmeticsdatabase.com](http://www.cosmeticsdatabase.com)  
(<http://www.cosmeticsdatabase.com>)<sup>7</sup>

- This site, created by the Environmental Working Group (an environmental and public health advocacy group), allows consumers to look up products of interest and determine which contain ingredients that have been associated with cancer, developmental problems, or other health effects in at least one lab study of animals or in a population-based study of humans.

**California Safe Cosmetics Program** Website:  
[www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/CSCP/Pages/CSCP.aspx](http://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/CSCP/Pages/CSCP.aspx)  
([www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/CSCP/Pages/CSCP.aspx](http://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/CSCP/Pages/CSCP.aspx))<sup>8</sup>

The primary purpose of the California Safe Cosmetics Program (CSCP) is to collect information on hazardous and potentially hazardous ingredients in cosmetic products sold in California and to make this information available to the public. Maintains a list of all cosmetic products sold in California that contain any ingredients known or suspected to cause cancer, birth defects, or other reproductive harm. Both cosmetic ingredients and cosmetic products can be researched at this site.

*\*Inclusion on this list does not imply endorsement by the American Cancer Society.*

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Last Medical Review: May 28, 2014 Last Revised: May 28, 2014

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