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TDD: 1-888-220-5446

Cosmetics and Your Health

Q: What are cosmetics? How are they different from over-the-counter (OTC) drugs?

A: Cosmetics are products people use to cleanse or change the look of the face or body.

Cosmetic products include:

- Skin creams
- Lotions
- Perfumes
- Lipsticks
- Fingernail polishes
- Eye and face make-up products
- Permanent waves
- hair dyes
- Toothpastes
- Deodorants

Unlike drugs, which are used to treat or prevent disease in the body, cosmetics do not change or affect the body's structure or functions.

Q: What's in cosmetics?

A: Fragrances and preservatives are the main ingredients in cosmetics. Fragrances are the most common cause of skin problems. More than 5,000 different kinds are used in products. Products marked "fragrance-free" or "without perfume" means that no fragrances have been added to make the product smell good.

Preservatives in cosmetics are the second most common cause of skin problems. They prevent bacteria and fungus from growing in the product and protect products from damage caused by air or light. But preservatives can also cause the skin to become irritated and infected. Some examples of preservatives are:

- Paraben
- Imidazolidinyl urea
- Quaternium-15
- DMDM hydantoin
- Phenoxyethanol
- Formaldehyde

The ingredients below cannot be used, or their use is limited, in cosmetics. They may cause cancer or other serious health problems.

- Bithionol
- Mercury compounds
- Vinyl chloride
- Halogenated salicylanilides
- Zirconium complexes in aerosol sprays
- Chloroform
- Methylene chloride
- Chlorofluorocarbon propellants
- Hexachlorophene

Q: What is the role of the Food and Drug Administration (FDA) in the cosmetic industry?

A: A cosmetic maker can sell products without FDA approval. FDA does not review or approve cosmetics, or their ingredients, before they are sold to the public. But FDA urges cosmetic makers to do whatever tests are needed to



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prove their products are safe. Cosmetics makers must put a warning statement on the front labels of products that have not been safety testing, which reads, "WARNING—The safety of this product has not been determined."

FDA does require safety testing for color additives used in cosmetics. Cosmetics may only contain approved and certified colors. You'll find FD&C, D&C, or external D&C listed on cosmetic labels.

- FD&C – color that can be used only in foods, drugs, and cosmetics
- D&C – color that can be used only in drugs and cosmetics
- External D&C – color that can be used only in drugs applied to the surface of the skin and cosmetics

A cosmetic maker also does not have to report product injuries. FDA collects this information on a voluntary basis only. Cosmetic makers that want to be a part of this program send reports to the FDA.

Product recalls are voluntary actions taken by cosmetic makers too. FDA cannot require cosmetics recalls. But FDA does monitor cosmetic makers that do a recall. FDA must first prove in court that a cosmetic product is a danger or somehow breaks the law before it can be taken off the market.

Q: Are cosmetics safe?

Yes, for the most part. Serious problems from cosmetics are rare. But sometimes problems can happen.

A: The most common injury from cosmetics is from scratching the eye with a mascara wand. Eye infections can result if the scratches go untreated. These

infections can lead to ulcers on the cornea (clear covering of the eye), loss of lashes, or even blindness. To play it safe, never try to apply mascara while riding in a car, bus, train, or plane.

Sharing make-up can also lead to serious problems. Cosmetic brushes and sponges pick up bacteria from the skin. And if you moisten brushes with saliva, the problem can be worse. Washing your hands before using make-up will help prevent this problem.

Sleeping while wearing eye make-up can cause problems too. If mascara flakes into your eyes while you sleep, you might wake up with itching, blood-shot eyes, infections, or eye scratches. So be sure to remove all make-up before going to bed.

Cosmetic products that come in aerosol containers also can be a hazard. For example, it is dangerous to use aerosol hairspray near heat, fire, or while smoking. Until hairspray is fully dry, it can catch on fire and cause serious burns. Fires related to hairsprays have caused injuries and death. Aerosol sprays or powders also can cause lung damage if they are deeply inhaled into the lungs.

To find out more about cosmetic safety, please visit FDA's cosmetics safety section at <http://www.fda.gov/Cosmetics/ProductandIngredientSafety/default.htm>.

Q: How can I protect myself against the dangers of cosmetics?

A:

- Never drive and put on make-up. Not only does this make driving a danger, hitting a bump in the road and scratching your eyeball can cause serious eye injury.



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- Never share make-up. Always use a new sponge when trying products at a store. Insist that salespersons clean container openings with alcohol before applying to your skin.
- Keep make-up containers closed tight when not in use.
- Keep make-up out of the sun and heat. Light and heat can kill the preservatives that help to fight bacteria. Don't keep cosmetics in a hot car for a long time.
- Don't use cosmetics if you have an eye infection, such as pinkeye. Throw away any make-up you were using when you first found the problem.
- Never add liquid to a product unless the label tells you to do so.
- Throw away any make-up if the color changes, or it starts to smell.
- Never use aerosol sprays near heat or while smoking, because they can catch on fire.
- Don't deeply inhale hairsprays or powders. This can cause lung damage.
- Avoid color additives that are not approved for use in the eye area, such as "permanent" eyelash tints and kohl (color additive that contains lead salts and is still used in eye cosmetics in other countries). Be sure to keep kohl away from children. It may cause lead poisoning.

Q: What are "cosmeceuticals?"

A: Some products can be both cosmetics and drugs. This may happen when a product has two uses. For example, a shampoo is a cosmetic because it's used to clean the hair. But, an anti-dandruff

treatment is a drug because it's used to treat dandruff. So an antidandruff shampoo is both a cosmetic and a drug. Other examples are:

- Toothpastes that contain fluoride
- Deodorants that are also antiperspirants
- Moisturizers and make-up that provide sun protection

These products must meet the standards for both cosmetics (color additives) and drugs.

Some cosmetic makers use the term "cosmeceutical" to refer to products that have drug-like benefits. FDA does not recognize this term. A product can be a drug, a cosmetic, or a combination of both. But the term "cosmeceutical" has no meaning under the law.

While drugs are reviewed and approved by FDA, FDA does not approve cosmetics. If a product acts like a drug, FDA must approve it as a drug.

Q: How long do cosmetics last?

A: You may not be able to use eye make-up, such as mascara, eyeliner, and eye shadow for as long as other products. This is because of the risk of eye infection. Some experts recommend replacing mascara three months after purchase. If mascara becomes dry, throw it away. Don't add water or, even worse, saliva to moisten it. That will bring bacteria into the product.

You may also need to watch certain "all natural" products that contain substances taken from plants. These products may be more at risk for bacteria. Since these products contain no preservatives or have non-traditional ones, your risk of infection may be greater.



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If you don't store these products as directed, they may expire before the expiration date. For example, cosmetics stored in high heat may go bad faster than the expiration date. On the other hand, products stored the way they should be can be safely used until they expire.

Q: What are hypoallergenic cosmetics?

A: Hypoallergenic (hy-po-al-ler-gen-ic) cosmetics are products that makers claim cause fewer allergic reactions than other products. Women with sensitive skin, and even those with "normal" skin, may think these products will be gentler. But there are no federal standards for using the term hypoallergenic. The term can mean whatever a company wants it to mean. Cosmetic makers do not have to prove their claims to the FDA.

Some products that have "natural" ingredients can cause allergic reactions. If you have an allergy to certain plants or animals, you could have an allergic reaction to cosmetics with those things in them. For example, lanolin from sheep wool is found in many lotions. But it's a common cause of allergies too.

Q: Can cosmetics cause acne?

A: Some skin and hair care products can cause acne. To help prevent and control acne flare-ups, take good care of your skin. For example, use a mild soap or cleanser to gently wash your face twice a day. Choose "non-comedogenic" make-up and hair care products. This means that they don't close up the pores.

Q: Are tattoos and permanent make-up safe?

A: FDA is looking into the safety of tattoos and permanent make-up since they are now more popular. The inks, or dyes, used for tattoos are color additives. Right now, no color additives have been approved for tattoos, including those used in permanent make-up.

You should be aware of these risks of tattoos and permanent make-up:

- Tattoo needles and supplies can transmit diseases, such as hepatitis C and HIV. Be sure all needles and supplies are sterile before they are used on you.
- Tattoos and permanent make-up are not easy to take off. Removal may cause a permanent change in color.
- Think carefully before getting a tattoo. You could have an allergic reaction.
- You cannot make blood donations for a year after getting a tattoo or permanent make-up.

Q: Are cosmetic products with alpha hydroxy acids safe?

A: Alpha hydroxy acids (AHAs) come from fruit and milk sugars. They are found in many creams and lotions. Many people buy products with AHAs, because they claim to reduce wrinkles, spots, sun-damaged skin, and other signs of aging. Some studies suggest they may work.

But are these products safe? FDA has received reports of reactions in people using AHA products. Their complaints include:

- Severe redness



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- Swelling (especially in the area of the eyes)
- Burning
- Blistering
- Bleeding
- Rash
- Itching
- Skin discoloration

AHAs may also increase your skin's risk of sunburn.

To find out if a product contains an AHA, look on the list of ingredients. By law, all cosmetics have ingredients on their outer label. AHAs may be called other names, like glycolic acid and lactic acid.

Q: What precautions should I follow when using AHA products?

A: If you want to use AHA products, follow these safety tips:

- Always protect your skin before going out during the day. Use a sunscreen with a SPF (sun protection factor) of at least 15. Wear a hat with a brim. Cover up with lightweight, loose-fitting, long-sleeved shirts, and pants.
- Buy products with good label information:
- A list of ingredients to see which AHA or other chemical acids are in the product
- The name and address of the maker
- A statement about the product's AHA and pH levels

The first two have to be on the label. The third is one is by choice. You can call or write the maker to find about a

product's AHA and pH levels.

- Buy only products with an AHA level of 10 percent or less and a pH of 3.5 or more.
- Test a small area of skin to see if it is sensitive to any AHA product before using a lot of it.
- Stop using the product right away if you have a reaction, such as stinging, redness, or bleeding.
- Talk with your doctor or dermatologist (a doctor that treats skin problems) if you have a problem. You also can report your reaction to the FDA. Write to: Office of Cosmetics and Colors (HFS-106), 5100 Paint Branch Parkway, College Park, MD 20740-3835. Or you can call them at (202) 401-9725.

Q: Are hair dyes safe?

A: The decision to change your hair color may be a hard one. Some studies have linked hair dyes with a higher risk of certain cancers, while other studies have not found this link. Most hair dyes also don't have to go through safety testing that other cosmetic color additives do before hitting store shelves. Women are often on their own trying to figure out whether hair dyes are safe.

When hair dyes first came out, the main ingredient in coal-tar hair dye caused allergic reactions in some people. Most hair dyes are now made from petroleum sources. But FDA still considers them to be coal-tar dyes. This is because they have some of the same compounds found in these older dyes.

Cosmetic makers have stopped using things known to cause cancer in animals. For example, 4-methoxy-m-



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phenylenediamine (4MMPD) or 4-methoxy-m-phenylenediamine sulfate (4MMPD sulfate) are no longer used. But chemicals made almost the same way have replaced some of the cancer-causing compounds. Some experts feel that these newer ingredients aren't very different from the things they're replacing.

Experts suggest that you may reduce your risk of cancer by using less hair dye over time. You may also reduce your risk by not dyeing your hair until it starts to gray.

Q: What precautions should I take when I dye my hair?

A: You should follow these safety tips when dyeing your hair:

- Don't leave the dye on your head any longer than needed.
- Rinse your scalp thoroughly with water after use.
- Wear gloves when applying hair dye.
- Carefully follow the directions in the hair dye package.
- Never mix different hair dye products.
- Be sure to do a patch test for allergic reactions before applying the dye to your hair. Almost all hair dye products include instructions for doing a patch test. It's important to do this each time you dye your hair. Your hairdresser should also do the patch test before dyeing your hair. To test, put a dab of hair dye behind your ear, and don't wash it off for two days. If you don't have any signs of allergic reaction, such as itching, burning, or redness at the test spot, you can be somewhat sure that you

won't have a reaction to the dye applied to your hair. If you do react to the patch test, do the same test with different brands or colors until you find one to which you're not allergic.

- Never dye your eyebrows or eyelashes. An allergic reaction to dye could cause swelling or increase risk of infection in the eye area. This can harm the eye and even cause blindness. Spilling dye into the eye by accident could also cause permanent damage. FDA bans the use of hair dyes for eyelash and eyebrow tinting or dyeing even in beauty salons.

Q: Are lead acetates safe in hair dyes?

A: Lead acetate is used as a color additive in "progressive" hair dye products. These products are put on over a period of time to produce a gradual coloring effect. You can safely use these products if you follow the directions carefully. This warning statement must appear on the product labels of lead acetate hair dyes:

"Caution: Contains lead acetate. For external use only. Keep this product out of children's reach. Do not use on cut or abraded scalp. If skin irritation develops, discontinue use. Do not use to color mustaches, eyelashes, eyebrows, or hair on parts of the body other than the scalp. Do not get in eyes. Follow instructions carefully and wash hands thoroughly after use."

Q: Is it safe to dye my hair when I'm pregnant?

A: We don't know much about the safety of hair dyes during pregnancy. It's



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likely that when you apply hair dye, only a small amount is absorbed into your system. So very little chemicals, if any, would be able to get to your baby. In the few animal and human studies

that have been done, no changes were seen in the developing baby. Talk with your doctor if you have questions or concerns. ■

For more information

For more information on cosmetics or hair dye, contact the National Women's Health Information Center at 800-994-9662 or the following organizations:

Food and Drug Administration (FDA), OPHS, HHS

Phone: (888) 463-6332 (Consumer Information)

Internet Address: <http://www.fda.gov>

Office of Cosmetics and Colors Automated Information Line, FDA, OPHS, HHS

Phone: (888) 723-3366

Internet Address: <http://vm.cfsan.fda.gov/~dms/cos-toc.html>

American Academy of Dermatology (AAD)

Phone: (888) 462-3376

Internet Address: <http://www.aad.org>

Mayo Foundation for Medical Education and Research Skin Center

Phone: (480) 301-8000

Internet Address: <http://www.mayoclinic.com>

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