



Eye Cosmetics and Eyebrow/Eyelash Dyes

Below are three short articles on eye products:

- 1. Eye Cosmetic Safety (also available in Arabic)
- 2. Eyelash Dyes
- 3. FDA Warns Against Use of "Permanent" Eyelash/Eyebrow Dyes and Tints

U. S. Food and Drug Administration Office of Cosmetics and Colors Fact Sheet August 1, 2001

Eye Cosmetic Safety

Eye cosmetics are intended to make eyes more attractive, or in some cases to cleanse the eye area. One thing they shouldn't do is cause harm. Most are safe when used properly. However, there are some things to be careful about when using these products, such as the risk of infection, the risk of injury from the applicator, and the use of unapproved color additives, such as kohl. The following information provides an introduction to some safety concerns and legal issues related to eye cosmetics.

Keep it clean!

Eye cosmetics are usually safe when you buy them, but misusing them can allow dangerous bacteria to grow in them. Then, when applied to the eye area, a cosmetic can cause an infection. In rare cases, women have been temporarily or permanently blinded by an infection from an eye cosmetic. See the Safety Checklist below for tips on keeping your eye cosmetics clean and protecting against infections.

Occasionally, contamination can be a problem for some eye cosmetics even when they are new. FDA has an <u>Import Alert in effect for cosmetics -- including eye cosmetics -- contaminated with harmful microorganisms</u>.

Don't share! Don't swap!

Don't share or swap eye cosmetics -- not even with your best friend. Another person's germs may be hazardous to you. The risk of contamination may be even greater with "testers" at retail stores, if a number of people are using the same sample product. If you feel you must sample cosmetics at a store, make sure they are applied with single-use applicators, such as clean cotton swabs.

Hold still!

It may seem like efficient use of your time to apply makeup in the car or on the bus, but resist that temptation, even if you're not in the driver's seat. If you hit a bump, come to a sudden stop, or are hit by another vehicle, you risk injuring your eye with a mascara wand or other applicator. Even a slight scratch can result in a serious infection.

What's in it?

As with any cosmetic product sold on a retail basis to consumers, eye cosmetics are required to have an ingredient declaration on the label, according to regulations implemented under the <u>Fair Packaging and Labeling Act</u>, or FPLA -- an important consumer protection law. If you wish to avoid certain ingredients or compare the ingredients in different brands, you can check the ingredient declaration.

If a cosmetic sold on a retail basis to consumers does not have an ingredient declaration, it is considered misbranded and is illegal in interstate commerce. Very small packages in tightly compartmented display racks may have copies of the ingredient declaration available on tear-off sheets accompanying the display. If neither the package nor the display rack provides the ingredient declaration, you aren't getting the information you're entitled to. Don't hesitate to ask the store manager or the manufacturer why not.

What's that shade you're wearing?

In the United States, the use of color additives is strictly regulated. A number of color additives approved for cosmetic use in general are not approved for use in the area of the eye. An import alert for cosmetics containing illegal colors lists several eye cosmetics.

Keep away from kohl -- and keep kohl away from kids!

One color additive of particular concern is kohl. Also known as al-kahl, kajal, or surma, kohl is used in

some parts of the world to enhance the appearance of the eyes, but is unapproved for cosmetic use in the United States. Kohl consists of salts of heavy metals, such as antimony and lead. It may be tempting to think that because kohl has been used traditionally as an eye cosmetic in some parts of the world, it must be safe. However, there have been reports linking the use of kohl to lead poisoning in children.*

An FDA Import Alert cites three main reasons for detaining imports of kohl:

- 1. For containing an unsafe color additive, which makes the product adulterated.
- 2. For labeling that describes the product falsely as "FDA Approved."
- 3. For lack of an ingredient declaration.

Some eye cosmetics may be labeled with the word "kohl" only to indicate the shade, not because they contain true kohl. If the product is properly labeled, you can check to see whether the color additives declared on the label are in FDA's <u>list of color additives approved for use in cosmetics</u>, then make sure they are listed as approved for use in the area of the eye.

Dying to dye your lashes?

Permanent eyelash and eyebrow tints and dyes have been known to cause serious eye injuries, including blindness. There are no color additives approved by FDA for permanent dyeing or tinting of eyelashes and eyebrows. FDA has an Import Alert in effect for eyelash and eyebrow dyes containing coal tar_colors. For more information on this subject, see Eyelash Dyes and FDA Warns Against Use of "Permanent" Eyelash/Eyebrow Dyes and Tints.

Safety Checklist

If you use eye cosmetics, FDA urges you to follow these safety tips:

- If any eye cosmetic causes irritation, stop using it immediately. If irritation persists, see a doctor.
- Avoid using eye cosmetics if you have an eye infection or the skin around the eye is inflamed. Wait until the area is healed. Discard any eye cosmetics you were using when you got the infection.
- Be aware that there are bacteria on your hands that, if placed in the eye, could cause infections.
 Wash your hands before applying eye cosmetics.
- Make sure that any instrument you place in the eye area is clean.
- Don't share your cosmetics. Another person's bacteria may be hazardous to you.
- Don't allow cosmetics to become covered with dust or contaminated with dirt or soil. Keep containers clean.
- Don't use old containers of eye cosmetics. Discard mascara three months after purchase.
- Discard dried-up mascara. Don't add saliva or water to moisten it. The bacteria from your mouth

may grow in the mascara and cause infection. Adding water may introduce bacteria and will dilute the preservative that is intended to protect against microbial growth.

- Don't store cosmetics at temperatures above 85 degrees F. Cosmetics held for long periods in hot cars, for example, are more susceptible to deterioration of the preservative.
- When applying or removing eye cosmetics, be careful not to scratch the eyeball or other sensitive area. Never apply or remove eye cosmetics in a moving vehicle.
- Don't use any cosmetics near your eyes unless they are intended specifically for that use. For instance, don't use a lip liner as an eye liner. You may be exposing your eyes to contamination from your mouth, or to color additives that are not approved for use in the area of the eye.
- Avoid color additives that are not approved for use in the area of the eye, such as "permanent" eyelash tints and kohl. Be especially careful to keep kohl away from children, since reports have linked it to lead poisoning.

For related information, see <u>Import Alerts</u> and the FDA Consumer Article <u>"Dangers of Lead Still</u> <u>Linger"</u>.

U. S. Food and Drug Administration Center for Food Safety and Applied Nutrition Office of Cosmetics and Colors Fact Sheet February 7, 1995

EYELASH DYES

1933 marked the beginning of a congressional controversy over the need for new and stronger food and drug laws. At the time, FDA had no authority to move against a cosmetic product called Lash Lure that was causing allergic reactions in many women. Two women, in fact, had suffered severe reactions to the product; one woman became blind and the second woman died.

The new Food, Drug and Cosmetic Act was passed in 1938 and "Lash Lure" was the first product seized under its authority.

Consumers should never dye their eyebrows or eyelashes. An allergic reaction to the dye could prompt swelling, inflammation, and susceptibility to infection in the eye area. These reactions can severely harm the eye and even cause blindness. FDA prohibits the use of hair dyes for eyebrow and eyelash tinting or dyeing, even in beauty salons and other establishments.

FDA has continuously warned the public about the use of coal-tar dyes on the eyebrows or eyelashes, stating that such use could cause permanent injury to the eyes, including blindness.

Eyelash and eyebrow dyes should not be confused with temporary colorings used around the eyes, such as mascara, eye shadow, eyebrow pencils and eye liners which contain colors that have been approved by FDA for use in the eye area.

U.S. Food and Drug Administration FDA Fact Sheet T92-31: July 14, 1992

FDA WARNS AGAINST USE OF "PERMANENT" EYELASH/EYEBROW DYES AND TINTS

The Food and Drug Administration today reissued its long-standing warning against "permanent" eyebrow and eyelash dyeing. The Food, Drug, and Cosmetic Act of 1938 prohibits the marketing of hair dyes for eyelash and eyebrow tinting or dyeing because this practice has been known to cause severe eye injuries and even blindness.

These dyes should not be confused with temporary coloring products used around the eyes--such as mascara, eye shadow, eyebrow pencils and eye liners--which can be used safely.

FDA's new warning was prompted by a recent report from the New York City area of an injury possibly associated with eyebrow and eyelash tinting. An informal FDA survey of beauty salon advertisements in the Washington, DC area following the report from New York indicates that some establishments are promoting "permanent" eyebrow and eyelash dyeing or tinting services.

Consumers should be aware that there are no natural or synthetic color additives approved by FDA for dyeing or tinting eyelashes and eyebrows--either for use in beauty salons or in the home. In fact, the law requires all hair dye products to include instructions for performing patch tests before use to identify for possible allergic reactions, and to carry warnings about the dangers of applying these products to eyebrows and eyelashes.

The health hazards of permanent eyelash and eyebrow dyes have been known for more than 60 years. These dyes have repeatedly been cited in scientific literature as capable of causing serious reactions when placed in direct contact with the eye. In two famous cases in 1933, a woman who used eyelash dye died, while another woman became blind in both eyes after suffering weeks of intense pain.

Despite these warnings, however, some beauty salons and other establishments apparently continue to promote this use of hair dyes. This practice most often occurs during the summer months as a means of

retaining eyebrow and eyelash coloring after outdoor activities such as swimming.

As recently as 10 years ago, FDA issued an import alert against the importation of foreign eyebrow and eyelash dye products. Although FDA's quick action helped to limit the distribution of these products, some injuries did occur.

To protect the public health, FDA will continue to work to prevent the importation and marketing of eyebrow and eyelash dyes. In addition, the agency will intensify its work with state and local health officials and the cosmetics industry to combat the misuse of hair dye products.

*References for Eye Cosmetics Safety Article:

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Cosmetics

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