



Cosmetics

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Product and Ingredient Safety

Product Information

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Tattoos & Permanent Makeup

November 29, 2000; Updated June 23, 2008

FDA considers the inks used in intradermal tattoos, including permanent makeup, to be cosmetics and considers the pigments used in the inks to be color additives requiring premarket approval under the Federal Food, Drug, and Cosmetic Act. However, because of other public health priorities and a previous lack of evidence of safety concerns, FDA traditionally has not exercised its regulatory authority over tattoo inks or the pigments used in them. The actual practice of tattooing is regulated by local jurisdictions.

FDA is aware of more than 150 reports of adverse reactions in consumers to certain permanent make-up ink shades, and it is possible that the actual number of women affected was greater. In addition, concerns raised by the scientific community regarding the pigments used in these inks have prompted FDA to investigate the safe use of tattoo inks. FDA continues to evaluate the extent and severity of adverse events associated with tattooing and is conducting research on inks. As new information is assessed, the agency will consider whether additional actions are necessary to protect public health.

In addition to the reported adverse reactions, areas of concern include tattoo removal, infections that result from tattooing, and the increasing variety of pigments and diluents being used in tattooing. More than fifty different pigments and shades are in use, and the list continues to grow. Although a number of color additives are approved for use in cosmetics, none is approved for injection into the skin. Using an unapproved color additive in a tattoo ink makes the ink adulterated. Many pigments used in tattoo inks are not approved for skin contact at all. Some are industrial grade colors that are suitable for printers' ink or automobile paint.

Nevertheless, many individuals choose to undergo tattooing in its various forms. For some, it is an aesthetic choice or an initiation rite. Some choose permanent makeup as a time saver or because they have physical difficulty applying regular, temporary makeup. For others, tattooing is an adjunct to reconstructive surgery, particularly of the face or breast, to simulate natural pigmentation. People who have lost their eyebrows due to alopecia (a form of hair loss) may choose to have "eyebrows" tattooed on, while people with vitiligo (a lack of pigmentation in areas of the skin) may use tattooing to help camouflage the condition.

Whatever the reason, consumers should be aware of the risks involved in order to make an informed decision.

What Risks Are Involved in Tattooing?

The following are the primary complications that can result from tattooing:

- **Infection.** Unsterile tattooing equipment and needles can transmit infectious diseases, such as hepatitis and skin infections caused by *Staphylococcus aureus* ("staph") bacteria*. Tattoos received at facilities not regulated by your state or at facilities that use unsterile equipment (or re-use ink) may prevent you from being accepted as a blood or plasma donor for twelve months.
- **Removal problems.** Despite advances in laser technology, removing a tattoo is a painstaking process, usually involving several treatments and considerable expense. Complete removal without scarring may be impossible.
- **Allergic reactions.** Although FDA has received reports of numerous adverse reactions associated with certain shades of ink in permanent makeup, marketed by a particular manufacturer, reports of allergic reactions to tattoo pigments have been rare. However, when they happen they may be particularly troublesome because the pigments can be hard to remove. Occasionally, people may develop an allergic reaction to tattoos they have had for years.
- **Granulomas.** These are nodules that may form around material that the body perceives as foreign, such as particles of tattoo pigment.
- **Keloid formation.** If you are prone to developing keloids -- scars that grow beyond normal boundaries -- you are at risk of keloid formation from a tattoo. Keloids may form any time you injure or traumatize your skin. *Micropigmentation: State of the Art*, a book written by Charles Zwerling, M.D., Annette Walker, R.N., and Norman Goldstein, M.D., states that keloids occur more frequently as a consequence of tattoo removal.
- **MRI complications.** There have been reports of people with tattoos or permanent makeup who experienced swelling or burning in the affected areas when they underwent magnetic resonance imaging (MRI). This seems to occur only rarely and apparently without lasting effects.

There also have been reports of tattoo pigments interfering with the quality of the image. This seems to occur mainly when a person with permanent eyeliner undergoes MRI of the eyes. Mascara may produce a similar effect. The difference is that mascara is easily removable.

The cause of these complications is uncertain. Some have theorized that they result from an interaction with the metallic components of some pigments.

However, the risks of avoiding an MRI when your doctor has recommended one are likely to be much greater than the risks of complications from an interaction between the MRI and tattoo or

permanent makeup. Instead of avoiding an MRI, individuals who have tattoos or permanent makeup should inform the radiologist or technician of this fact in order to take appropriate precautions and avoid complications.

A Common Problem: Dissatisfaction

A common problem that may develop with tattoos is the desire to remove them. Removing tattoos and permanent makeup can be very difficult.

Although tattoos may be satisfactory at first, they sometimes fade. Also, if the tattooist injects the pigments too deeply into the skin, the pigments may migrate beyond the original sites, resulting in a blurred appearance.

Another cause of dissatisfaction is that the human body changes over time, and styles change with the season. The permanent makeup that may have looked flattering when first injected may later clash with changing skin tones and facial or body contours. People who plan to have facial cosmetic surgery are advised that the appearance of their permanent makeup may become distorted. The tattoo that seemed stylish at first may become dated and embarrassing. And changing tattoos or permanent makeup is not as easy as changing your mind.

Consult your healthcare provider about the best removal techniques for you.

What About Temporary Tattoos?

Temporary tattoos, such as those applied to the skin with a moistened wad of cotton, fade several days after application. Most contain color additives approved for cosmetic use on the skin. However, the agency has issued an [import alert for certain foreign-made temporary tattoos](#).

The temporary tattoos subject to the import alert are not allowed into the United States because they don't carry the FDA-mandated ingredient labels or they contain colors not permitted by FDA for use in cosmetics applied to the skin. FDA has received reports of allergic reactions to temporary tattoos.

In a similar action, FDA has issued an [import alert for henna intended for use on the skin](#). Henna is approved only for use as a hair dye, not for direct application to the skin. Also, henna typically produces a reddish brown tint, raising questions about what ingredients are added to produce the varieties of colors labeled as "henna," such as "black henna" and "blue henna." FDA has also received reports of allergic reactions to products applied to the skin that contain henna.

Reporting Adverse Reactions

FDA urges consumers and healthcare providers to report adverse reactions to tattoos and permanent makeup, problems with removal, or adverse reactions to temporary tattoos. Consumers and healthcare providers can register complaints using the contact information in [Your Guide to Reporting Problems to FDA](#).

For more information, see [Tattoos and Permanent Makeup](#).

* For related information on infections from tattooing, see the following documents from the Centers for Disease Control: [Viral Hepatitis B Fact Sheet](#) and ["Methicillin-Resistant Staphylococcus aureus Skin Infections Among Tattoo Recipients --- Ohio, Kentucky, and Vermont, 2004-2005"](#) (published in *Morbidity and Mortality Weekly Report*, June 23, 2006).

Anderson v. City of Hermosa Beach,
No. 08-56914 archived on September 10, 2010

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