



U.S. Food & Drug Administration

For Consumers

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Nail Care Products

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There are many nail products on the market. It is important to know how to use them safely. As with any cosmetic product, follow the labeled directions carefully and pay careful attention to any warning statements. The following information will answer commonly asked questions about some nail products and ingredients.

How Nail Products Are Regulated

Nail products for both home and salon use are regulated by the Food and Drug Administration. Under the Federal Food, Drug, and Cosmetic Act¹ (FD&C Act), these products are cosmetics [FD&C Act, section 201(i)].

By law, nail products sold in the United States must be free of poisonous or deleterious (harmful) substances that might injure users when used as labeled or under the usual or customary conditions of use (see Key Legal Concepts: Interstate Commerce, Adulteration and Misbranding²). Many nail products contain potentially harmful ingredients, but are allowed on the market because they are safe when used as directed. For example, some nail ingredients are harmful only when ingested, which is not their intended use.

The labels of all cosmetics, whether marketed to consumers or salons, must include a warning statement whenever necessary or appropriate to prevent a health hazard that may occur with use of the product (21 CFR 740.1³). Cosmetics sold on a retail basis to consumers also must bear an ingredient declaration, with the names of the ingredients listed in descending order of predominance. The requirement for an ingredient declaration does not apply, for example, to products used at professional establishments or samples distributed free of charge. However, the requirement does apply if these products are also sold at retail, even if they are labeled "For professional use only" (see Cosmetic Labeling: An Overview⁴).

Under the law, cosmetic products and ingredients, including nail products, are not subject to FDA premarket approval authority, with the exception of most color additives. However, FDA may pursue enforcement action against violative products, or against firms or individuals who violate the law (See FDA Authority Over Cosmetics⁵).

While FDA regulates the nail products intended for use at home and in salons, the operation of nail salons and the licensing of their technicians are regulated by state and local authorities. Also, the Occupational Safety and Health Administration⁶ has addressed the safety of employees in nail salons.

Nail Product Ingredient Safety

Infections and allergic reactions can occur with some nail products. As mentioned previously, some ingredients in nail products may be harmful if ingested. Some can easily catch fire if exposed to the flame of the pilot light of a stove, a lit cigarette, or other heat source, such as the heating element of a curling iron. Nail products also can be dangerous if they get in the eyes. Consumers should read labels of nail products carefully and heed any warnings.

Some Common Nail Product Ingredients

Acetonitrile in Artificial Nail Removers

Artificial nail removers consist primarily of acetonitrile. Child-resistant packaging is required for all household glue removers in liquid form containing more than 500 milligrams of acetonitrile in a single container [16 CFR 1700.14 (18)]. The Consumer Product Safety Commission (CPSC) enforces this requirement under authority of the Poison Prevention Packaging Act [15 U.S.C. 1471-1476]. However, the fact that a product is in "child-resistant" packaging does not mean that a child could not open it.

Like any cosmetic product that may be hazardous if misused, it is important for these artificial nail removers to carry an appropriate warning on the label, along with directions for safe use.

Formaldehyde in Nail Hardeners

Nail hardeners that contain formaldehyde may cause an irritation or allergic reaction to those sensitized to this compound. There is also some evidence that certain individuals may become allergic to toluene sulfonamide-formaldehyde resin, a common ingredient in nail preparations.

In 1984, the Cosmetic Ingredient Review (CIR) Expert Panel* reported that available toxicological data and other information were insufficient to conclude that cosmetics containing formaldehyde in excess of 0.2% are safe. However, the CIR was referring to cosmetic products applied to the skin, not nail products. The concentration of formaldehyde needed for nail hardening is higher than 0.2%, but formaldehyde is less likely to cause skin sensitization when shields are used to keep the hardener away from the skin. If you are allergic to formaldehyde, have previously experienced an allergic reaction to nail preparations or for any other reason wish to avoid this ingredient, be sure to read the product ingredient statement on the label to determine if formaldehyde and toluene sulfonamide-formaldehyde resin are present.

Methacrylate Monomers in Artificial Nails ("Acrylics")

Artificial nails are composed primarily of acrylic polymers and are made by reacting together acrylic monomers, such as ethyl methacrylate monomer, with acrylic polymers, such as polymethylmethacrylate. When the reaction is completed, traces of the monomer are likely to remain in the polymer. For example, traces of methacrylate monomers remain after artificial nails are formed. The polymers themselves are typically quite safe, but traces of the reactive monomers could result in an adverse reaction, such as redness, swelling, and pain in the nail bed, among people who have become sensitive (allergic) to methacrylates.

Ethyl methacrylate monomer is commonly used today in acrylic nails, although methyl methacrylate monomer may still be found in some artificial nail products. In the early 1970s, FDA received a number of complaints of injury associated with the use of artificial nails containing methyl methacrylate monomer. Among these injuries were reports of fingernail damage and deformity, as well as contact dermatitis. Unlike methyl methacrylate monomer, methyl methacrylate polymers were not associated with these injuries. Based on its investigations of the injuries and discussions with medical experts in the field of dermatology, the agency chose to remove from the market products containing 100 percent methyl methacrylate monomer through court proceedings, which resulted in a preliminary injunction against one firm as well as several seizure actions and voluntary recalls. No regulation specifically prohibits the use of methyl methacrylate monomer in cosmetic products.

The CIR Expert Panel determined in 2002 that ethyl methacrylate is safe as used when application is accompanied by directions to avoid skin contact because of its sensitizing potential (that is, the possibility that a person might develop an allergy to this material).

Methacrylic Acid in Nail Primers

Despite the similar names, methacrylic acid is different from methacrylate monomers. It also is used differently and raises different safety concerns. Methacrylic acid (MAA) has been used in nail primers to help acrylic nails adhere to the nail surfaces. In response to cases of poisoning and injury, the CPSC issued a regulation [16 CFR 1700.14 (29)] requiring child-resistant packaging for household products containing MAA. A number of serious injuries have occurred to children who ingested such products or spilled them, receiving burns to their skin.

Nail primers that contain MAA are most commonly distributed through wholesale suppliers to nail salons and retail beauty supply stores, and they usually are labeled "For Professional Use Only." However, some of these retail stores sell to both professionals and consumers.

The CPSC regulation, established in accordance with the Poison Prevention Packaging Act, requires child-resistant packaging for liquid household products containing more than 5 percent MAA, weight to volume, in a single retail package. That means that it applies, for example, to a product containing more than 5 grams of MAA per 100 milliliters.

MAA products applied by means of absorbent material in a dispenser, such as a pen-like marker, are exempt from this requirement if there is no free liquid in the device and if, under any reasonably foreseeable conditions of use, the methacrylic acid will emerge only through the tip of the device. For more information regarding the child-resistant packaging requirements for MAA, contact the Office of Compliance, CPSC, at (301) 504-0608.

Phthalates

Phthalates are a group of chemicals used in a wide variety of products, from toys to carpeting and medical tubing. In nail polishes, they are used primarily at concentrations of less than 10% as plasticizers, to reduce cracking by making them less brittle. Dibutylphthalate (DBP) is used most commonly in nail polishes, but dimethylphthalate (DMP) and diethylphthalate (DEP) are used occasionally. For information on health questions related to phthalates in cosmetics, please see Phthalates and Cosmetic Products⁷.

Toluene in Nail Polishes and Other Products

Toluene is used as a solvent in a variety of nail products, such as nail polish, nail hardeners, and polish removers. Toluene was reviewed by the CIR Expert Panel in 1987, when the Panel determined that it was safe for cosmetic use in nail products when limited to concentrations no greater than 50 percent. The Panel re-evaluated the safety of toluene in 2005 and confirmed its original conclusion.

Reporting Adverse Nail Product Reactions

Consumers, nail technicians, and healthcare providers can report adverse reactions from nail products using the contact information in Bad Reaction to Cosmetics? Tell FDA⁸.

* The Cosmetic Ingredient Review (CIR) Expert Panel is an independent, industry-funded panel of medical and toxicology experts that meets quarterly to conduct safety assessments of cosmetic ingredients and publishes its findings in peer-review journals. FDA participates in the CIR in a non-voting capacity.

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Cosmetics

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