

## *How Safe are Color Additives?*

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I receive calls from time to time about food additives and their safety. I want to share with you information from a recent article published by the USDA regarding these color additives. **What are color additives?** Color additives give the red tint to your fruit punch and the green hue to your mint-flavored toothpaste. They are dyes, pigments, or other substances that can impart color when added or applied to a food, drug, cosmetic, or the human body. They can be found in a range of consumer products— from cough syrup and eyeliner to contact lenses and cereal.

**So how safe are they?** “Color additives are very safe when used properly,” says Linda Katz, M.D., M.P.H., Director of the Office of Cosmetics and Colors in FDA’s Center for Food Safety and Applied Nutrition (CFSAN). “There is no such thing as absolute safety of any substance. In the case of a new color additive, FDA determines if there is a reasonable certainty of no harm under the color additive’s proposed conditions of use.” Here are more facts you should know about color additive safety.

**FDA regulates color additives used in the United States.** This includes those used in food (and dietary supplements), drugs, cosmetics, and medical devices. These color additives (except coal-tar hair dyes) are subject by law to approval by the agency and must be used only in compliance with the approved uses, specifications, and restrictions. In the approval process, FDA evaluates safety data to ensure that a color additive is safe for its intended purposes. Color additives that FDA has found to cause cancer in animals or humans may not be used in FDA-regulated products marketed in the United States.

**Two main categories make up FDA’s list of permitted color additives—certifiable and exempt.** **Certifiable** color additives are man-made, derived primarily from petroleum and coal sources. Only after a batch sample meets certification requirements can it be used legally in FDA-regulated products. Certified color additives have special names consisting of a prefix, such as FD&C, D&C, or Ext. D&C; a color; and a number. For example, FD&C Yellow No. 6, is often found in cereals, ice cream, and baked goods. Sometimes a color additive is identified by a shortened form of its name, consisting of just the color and number, such as Yellow 6.

The second main category of color additives are “**exempt**” from batch certification, and are obtained largely from plant, animal, or mineral sources. Examples include caramel color and grape color extract. Though they are not subject to batch certification requirements, they are still artificial color additives and must comply with regulatory requirements.

**Approval of a color additive for one intended use does not mean approval for other uses.** For example, no color additives have been approved for injection into the skin— even though tattoo parlors often claim that the pigments in their inks are “FDA-approved.” Likewise, no color additives are approved for permanent makeup (a form of tattooing). And henna is approved for use on the hair, but not the skin.

**Reactions to color additives are rare.** It is possible, but rare, to have an allergic-type reaction to a color additive. For example, FD&C Yellow No. 5, widely found in beverages, desserts, processed vegetables, drugs, makeup, and other products, may cause itching and hives in some people. The FDA requires all products containing this dye to identify it on their labels so that consumers who are sensitive to the dye can avoid it. On medicine labels, this certified color additive is identified by the name, "tartrazine."

**FDA can take action against companies if there are violations.** In the absence of a voluntary recall, the FDA may choose to seize such products that do not comply with regulatory standards. For example, imported cosmetic products offered for entry into the United States may be detained until a regulatory investigation is completed. Consumers should beware of cosmetics and foods marketed abroad because they are not subject to the same safeguards as those marketed in the United States. For more information on color additives visit the FDA's Color Additives Web Page at [www.cfsan.fda.gov/~dms/col-toc.html](http://www.cfsan.fda.gov/~dms/col-toc.html), or call the Hardee County Extension Service Office at 863-773-2164.