How Safe 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.

Photo Illustration: FDA/Michael Ermarth

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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. In addition to undergoing approval, some color additives are known as "certifiable." Certifiable color additives are man-made, derived primarily from petroleum and coal sources. The manufacturer submits a sample from the batch for which it is requesting certification, and FDA tests the sample to determine whether it meets the color additive's requirements for composition and purity. If it does, FDA "certifies" the batch and issues a certification lot number. Only then can that batch 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. An example is FD&C Yellow No. 6, 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.

Other color additives, in the second main category, are "exempt" from batch certification. These are obtained largely from plant, animal, or mineral sources. Examples include caramel color and grape color extract. They are not subject to batch certification requirements, but they are still artificial color additives and must comply with regulatory requirements. Both types of color additives are subject to rigorous safety standards.

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 may cause itching and hives in some people. This color additive is widely found in beverages, desserts, processed vegetables, drugs, makeup, and other products. FDA requires all products containing FD&C Yellow No. 5 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 also identified by its uncertified name, "tartrazine."

FDA can take action against companies if there are violations. In the absence of a voluntary action such as a product recall, FDA can issue warning letters, detentions, and import alerts for products that are found to be unsafe or to contain color additives that are prohibited, misused, or not properly identified as ingredients. FDA can also seize such products. Color additive violations are a common reason for detaining imported cosmetic products that are offered for entry into the United States. Color additives in foods and cosmetics marketed abroad are not subject to the same safeguards as those marketed in the United States.

FDA monitors reports of problems related to color additives. Report adverse reactions to color additives to your nearest FDA district office at *www.fda.gov/opacom/backgrounders/complain.html*

Or, report problems to CFSAN's Adverse Event Reporting System (CAERS) by phone at 301-436-2405 or email at *CAERS@cfsan.fda.gov*

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For More Information

FDA's Color Additives Web Page
www.cfsan.fda.gov/~dms/col-toc.html

Color Additives for Specific Product Categories
www.cfsan.fda.gov/~dms/col-prod.html#cosmetics

Summary of Color Additives Listed for Use in the United States in Foods, Drugs, Cosmetics, and Medical Devices
www.cfsan.fda.gov/~dms/opa-col2.html

Color Additives: FDA's Regulatory Process and Historical Perspectives
www.cfsan.fda.gov/~dms/col-regu.html