

California Safe Cosmetics Program Informational Sheet

Definitions

Please refer to the Federal Food, Drug, and Cosmetic Act and regulations implemented by the U.S. Food and Drug Administration (U.S. FDA): <http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm>

Cosmetic

According to § 201 (i) of the Federal Food, Drug and Cosmetics Act (21 U.S. C § 321 (i)), *cosmetic* is defined as “(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.”

Cosmetic Product

According to 21 Code of Federal Regulations (CFR) § 700.3 (b), a *cosmetic product* is defined as “a finished cosmetic the manufacture of which has been completed. Any cosmetic product which is also a drug or device or component thereof is also subject to the requirements of Chapter V [drugs and devices] of the act.”

Cosmetic-Drug

U.S. FDA provides the following explanation of a cosmetic-drug (www.cfsan.fda.gov/~dms/cos-218.html): “Some products meet the definitions of both cosmetics and drugs. This may happen when a product has two intended uses. For example, a shampoo is a cosmetic because its intended use is to cleanse the hair. An antidandruff treatment is a drug because its intended use is to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug. Among other cosmetic/drug combinations are toothpastes that contain fluoride, deodorants that are also antiperspirants, and moisturizers and makeup marketed with sun-protection claims. Such products must comply with U.S. FDA requirements for both cosmetics and drugs.”

Soap

U.S. FDA provides the following explanation of a cosmetic-drug (www.cfsan.fda.gov/~dms/cos-218.html): “Not every product marketed as soap meets FDA's definition of the term. FDA interprets the term "soap" to apply only when – 1) The bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the product's detergent properties are due to the alkali-fatty acid compounds, and 2) the product is labeled, sold, and represented solely as soap [21 CFR 701.20].”

Ingredient

According to 21 CFR § 700.3 (e), an *ingredient* is defined as “any single chemical entity or mixture used as a component in the manufacture of a cosmetic product.”

Incidental Ingredients

FDA regulation, 21 CFR § 701.3 (l), states that “The provisions of this section do not require the declaration of incidental ingredients that are present in a cosmetic at insignificant levels and that have no technical or functional effect in the cosmetic. For the purpose of this paragraph, *incidental ingredients* are:”

- “Substances that are added to a cosmetic during the processing of such cosmetic but are removed from the cosmetic in accordance with good manufacturing practices before it is packaged in its finished form.” [Example: Filter aid.]
- “Substances that are added to a cosmetic during processing for their technical or functional effect in the processing, are converted to substances the same as constituents of declared ingredients, and do not significantly increase the concentration of those constituents.” [Example: Sodium hydroxide added to a sodium stearate and stearic acid-containing cosmetic.]

- “Substances that are added to a cosmetic during the processing of such cosmetic for their technical and functional effect in the processing but are present in the finished cosmetic at insignificant levels and do not have any technical or functional effect in that cosmetic.” [Example: Defoaming agent.]
- “Substances that have no technical or functional effect in the cosmetic but are present by reason of having been incorporated into the cosmetic as an ingredient of another cosmetic ingredient.”

Note: The California Safe Cosmetics Program (CSCP) in the Department of Public Health (CDPH) developed this Informational Sheet primarily in response to questions stakeholders have raised about the California Safe Cosmetics Act of 2005 (the Act). It was developed with input from the CDPH Office of Legal Services. It is predominantly a compilation of material from either the Act or federal rules that are referenced in the Act. These CDPH determinations on what the law means have been taken either directly from the law itself, or is what CDPH has concluded embodies the only legally tenable interpretation of the Act. Thus, actions of CDPH in implementing the Act do not constitute formal rulemaking (see California Government Code Section 11340.9).