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A Guide to United States Cosmetic Products Compliance Requirements

NIST
National Institute of Standards and Technology
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Disclaimer

Certain commercial entities are identified in this paper to specify the experimental procedure adequately. Such identification is not intended to imply recommendation or endorsement by the National Institute of Standards and Technology, nor is it intended to imply that the materials or equipment identified are necessarily the best available for the purpose.

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How To Use This Guide

- Regulations are mandatory
- Standards are voluntary (unless "Incorporated by Reference" in a regulation)
- Guidelines may be voluntary (but are often *de facto* industry standards)
- "**Red**" text highlights mandatory requirements
- "**Blue**" text indicates a hyperlink to a website, page, or document on the web

Scope

This guide addresses the compliance requirements for basic cosmetics and soap. The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines cosmetics as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body ... for cleansing, beautifying, promoting attractiveness, or altering the appearance" (FD&C Act, sec. 201(i)). Cosmetic products may include skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial make-up preparations, cleansing shampoos, permanent waves, hair colors, and deodorants, as well as any substance that is intended for use as a component of a cosmetic product.

This guidance document does not cover drugs or over-the-counter (OTC) drug products (like anti-dandruff shampoos) or products that have both cosmetic and drug properties, *excluding sunscreens,* which are covered in this guide. The FDA defines a drug as any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or that affects the structure or function of the body.

This guide also does not cover compliance requirements for toys that may be included with children's cosmetics.

For more information, see FDA's:
Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)

Overview of U.S. Federal Regulatory Framework

Once a law has been enacted by Congress, the appropriate federal agency (e.g., the Consumer Product Safety Commission, the Federal Trade Commission, the National Highway Traffic and Safety Administration, *et al*.) may create the regulations to implement the law. Before such regulations can be adopted, the appropriate federal agency ordinarily will issue a notice of proposed rulemaking (NPRM) to solicit public comments on the proposed rules. To provide opportunity for public comment, the appropriate federal agency must issue draft regulations or "Proposed Rules" that are published in the *Federal Register* (and that subsequently are notified as World Trade Organization Agreement on Technical Barriers to Trade (WTO TBT) notifications by the U.S. WTO TBT Notification Authority at NIST). The agency carefully reviews each comment and modifies the proposed rule, as appropriate, based on the record. The agency can then issue a Final Rule that also is published in the *Federal Register*, and later, published annually in the *Code of Federal Regulations (CFR)*. Together, the enabling acts and laws (published in the *United States Code (USC)* once passed) and the final regulations (published in the *CFR*) provide a framework for the implementation and enforcement of most federal laws in the United States.

Federal Regulatory Authorities and Technical Regulations (Mandatory)

Agency	Scope
Consumer Product Safety Commission (CPSC)	Product safety, children's products, child-resistant closures, soap
Customs and Border Protection (CBP)	Country of origin (for most imported products, licensing, and composition)
Environmental Protection Agency (EPA)	Federal Insecticide, Fungicide, and Rodenticide Act; ozone depleting substances
Federal Trade Commission (FTC)	Unfair trade practices, environmental and product performance claims
Food and Drug Administration (FDA)	Cosmetics regulations, microbeads, color additives, cosmetic ingredient regulations, cosmetic packaging and labeling (including CPSC requirements for cosmetics)
United States Department of Agriculture (USDA)	Organic claims

Consumer Product Safety Commission (CPSC)

Consumer Product Safety Act (CPSA)

Title 15, United States Code, Chapter 47, Sections 2059-2089

The Consumer Product Safety Act (CPSA), entered into law on October 27, 1972, was enacted to establish the Consumer Product Safety Commission (CPSC) and define its authority with the purpose of protecting the public against unreasonable risks of injury associated with consumer products; assisting consumers in evaluating the comparative safety of consumer products; developing uniform safety standards for consumer products; and promoting research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.

Child-Resistant Packaging

The Poison Prevention Packaging Act gives CPSC the authority to regulate child-resistant (CR) packaging. The Act, along with the Regulations, 16 CFR 1700, are designed to reduce the risk of children under five ingesting potentially hazardous household substances by requiring CR packaging for specific substances. CR, or special packaging as it is called in the Regulations, is packaging that is designed or constructed to be significantly difficult (within a reasonable time) for children under five years of age to open or access a toxic or harmful amount of the substance. CR packaging cannot be difficult for most adults to use properly.

Per the Regulations, certain substances are required to have CR packaging, including but not limited to:

- Methyl salicylate - liquid preparations containing more than 5 percent by weight
- Methanol - liquid form containing 4 percent or more by weight
- Ethylene glycol - liquid forms containing 10 percent or more by weight
- Glue removers containing acetonitrile - liquid forms containing more than 500 milligrams of acetonitrile in a single container
- Methacrylic acid - liquid form containing more than 5 percent (weight-to-volume) in a single retail package
- Non-emulsion liquid products that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100°F

See the Regulations for additional substances and exceptions.

CR packaging must meet the performance specifications outlined in 16 CFR 1700.15 by testing as detailed in 16 CFR 1700.20.

The Regulation allows the manufacturer or packer to package a nonprescription product subject to special packaging standards in one size of non-CR packaging, only if the manufacturer (or packer) also supplies the substance in CR packages of a popular size, and the non-CR packages bear conspicuous labeling stating: “This package for households without young children.”

The U.S. manufacturer or importer must supply a General Certificate of Conformity for CR packaging that is based on testing of each product or a reasonable testing program.

For additional information, see CPSC's webpage:
Poison Prevention Packaging Act
Poison Prevention Act Business Guidance
Consumer Product Safety Act
General Certificate of Conformity

Soap

The FD&C Act specifically excludes soap from the definition of a cosmetic, and it is, therefore, regulated for safety by the CPSC under the Federal Hazardous Substance Act (FHSA), 15 U.S.C. 1261. Per 21 CFR 701.20, the FDA interprets the term soap to apply only to articles that meet the following:

- The bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids, and the detergent properties of the article are due to the alkali-fatty acid compounds; and
- The product is labeled, sold, and represented only as soap.

Products intended for cleansing the human body that are not soap (as defined above) are considered cosmetics (e.g., intended to moisturize or deodorize the body) or drugs (e.g., intended to treat skin conditions or make antimicrobial claims) and are subject to the appropriate requirements of the FD&C Act and FDA regulations. If no claims are made, other than being soap, ingredient labeling is only required for any ingredient that would be related to one of the hazards addressed under the FHSA. However, **soap is subject to the requirements of the Fair Packaging and Labeling Act (FPLA) as administered by the FTC.**

Consumer Product Safety Improvement Act of 2008 (CPSIA)

Public Law 110–314, August 14, 2008

On August 14, 2008, the President signed into law Public Law 110-314 (Consumer Product Safety Improvement Act of 2008). On August 12, 2011, he signed into law amendments to the Act, Public Law 112–28, August 12, 2011. The Act provided CPSC with significant new regulatory and enforcement tools as part of amending and enhancing several CPSC statutes, including the Consumer Product Safety Act.

The Consumer Product Safety Improvement Act (CPSIA) provides additional requirements for children's products, including limits on specific substances. The CPSIA sets limits for lead content and phthalates in toys, child-care articles, and substances. A children's product is defined as a consumer product designed or intended primarily for children age 12 years or younger.

Children's Cosmetics

The regulation of cosmetics is generally outside the jurisdiction of the CPSC. However, with respect to children's toys that include cosmetics, Section 101(a) of the CPSIA **restricts the toy and any children's product, as defined in the statute, to a lead content limit of 100 parts per million (ppm).** In addition, the use of paint or similar surface coating on children's products **must not exceed a lead content limit of 90 ppm. The packaging of children's cosmetics is subject to the limits on lead content and lead in paint and similar surface coatings.**

Additionally, Section 108 of CPSIA states that certain children's toys and child-care articles cannot contain more than 0.1% of six phthalates – di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP) limits are applicable to both toys and child care items, whereas diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP) limits are applicable only to child-care articles and toys that are intended for children age three and younger and can be placed in the mouth.

Although children's cosmetics not packaged with a child's toy are subject to the appropriate requirements of the FD&C Act and FDA regulations, **packaging and containers holding children's cosmetics are subject to CPSIA compliance** whether or not they are packaged with toys. Toys are subject to testing and certification, which is not within the scope of this guide.

Federal Hazardous Substances Act (FHSA)

Title 15, United States Code, Chapter 30, Sections 1261-1278
16 CFR 1500, Federal Hazardous Substances Act (FHSA) Regulations

The Federal Hazardous Substances Act (FHSA), and regulations issued under it, set forth requirements for hazardous substances that are intended or packaged in a form suitable for use in the household. The FHSA's definition of "hazardous substance" excludes products that are considered cosmetics under the FD&C Act. However, products that meet FDA's definition of "soap" are not cosmetics and thus are subject to the FHSA. Cosmetics may be deemed misbranded under the FD&C Act unless the product label follows FDA guidance on ingredients, warnings, and the classification of a product based upon its function to beautify.

The FHSA **requires** household substances that meet the definition of hazardous (as defined in the Act) **to bear cautionary labeling to warn the consumer of the hazard(s) associated with the use of the product, instructions for safe use and storage, first aid instructions where applicable, and the statement "keep out of the reach of children."** Whether a product's label must bear cautionary labeling depends on its formulation and the likelihood that consumers will be exposed to any hazards the product presents in customary use, which includes ingestion by children. The FHSA defines as a banned hazardous substance those products that are intended for use by children and present an electrical, mechanical, or thermal hazard, with some exceptions. The Act also allows the CPSC to ban certain products that are so dangerous or the nature of the hazard is such that the labeling required by the Act is not adequate to protect consumers.

Customs and Border Protection (CBP)

Country of Origin: Marking of Imported Articles and Containers
Title 19, United States Code, Chapter 4, Section 1304
All products imported into the U.S. **must conform** to 19 CFR 134, Country of Origin Marking Regulations. These Regulations require that every article of foreign origin (or its container) that is imported into the U.S. be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article (or container) will permit, and in such a manner as to indicate to the ultimate purchaser in the U.S., the English name of the country of origin of the article at the time of importation.

> ***For more detailed information, see CBP's:***
> Importing cosmetics, soap, lotion, shampoo, medical and dental instruments for resale / commercial purposes

Environmental Protection Agency (EPA)

Many laws and regulations govern import and export requirements of materials that may pose a risk to human health and the environment. The Environmental Protection Agency (EPA) works with the states, other federal agencies, and foreign governments to ensure compliance with laws governing the import and export of many of these materials.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides for federal regulation of the distribution, sale, and use of pesticides to protect human health and the environment. **Products that kill or repel bacteria, germs, or insects are considered pesticides and must be registered with and evaluated for safety by the EPA prior to their distribution or sale**. The EPA will not register a pesticide until it has been tested to show that it will not pose an unreasonable risk when used according to the product's directions. This includes pesticides in cosmetics that provide antimicrobial or other pesticidal characteristics.

FIFRA does not allow companies to make public health pesticidal claims for any product distributed or sold unless the product has been approved and registered by EPA or is covered by an exemption from registration. The EPA will take action against companies that make such unlawful claims.

Products using essential oils such as citronella or peppermint are also covered under the Regulation, but may be considered minimum risk and be exempted from FIFRA registration.

> ***For more detailed information, see EPA's***
> Summary of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),
> Pesticide Registration notices by Year,
> Regulating Pesticides,

Pesticide Product Labels,
Regulation of Skin-Applied Repellents, and
Minimum Risk Pesticides Exempted from FIFRA Registration

Non-Essential Products Containing Chlorofluorocarbons (CFCs) and Hydrochlorofluorocarbons (HCFCs)

In the United States, ozone-depleting substances are regulated as Class I or Class II controlled substances.

- Class I substances have a higher ozone-depleting potential and have been completely phased out in the U.S., except for exemptions allowed under the Montreal Protocol.
- Class II substances, hydrochlorofluorocarbons (HCFCs), which were transitional substitutes for many Class I substances, are currently being phased out.

As a party to the Montreal Protocol, the U.S. must phase out the use of HCFCs completely by 2030. Section 605 of the Clean Air Act sets forth a schedule for the phaseout of HCFC production and consumption, and places restriction on HCFC use.

40 CFR 82 Subpart E sets forth specific labeling requirements, including a warning statement for products that contain a Class I or Class II substances. **Each product containing a Class I or Class II substance must bear the following warning statement, meeting the requirements for placement and form:**

> **WARNING: Contains [or Manufactured with, if applicable] [*insert name of substance*], a substance which harms public health and environment by destroying ozone in the upper atmosphere.**

For more detailed information see EPAs
Phaseout of HCFCs (Class II Ozone-Depleting Substances)
Prohibited and Restricted Ingredients

Volatile Organic Compounds (VOCs) and High-Volatility Organic Compounds (HVOCs)

40 CFR 59 Subpart C, *National Volatile Organic Compound Emission Standards for Consumer Products,* **establishes limits for VOCs and HVOCs** in consumer products including hairsprays, hair mousses, hair styling gels, nail polish removers, shaving cream, antiperspirants, and deodorants.

In addition, the container or package of each consumer product that is subject to this subpart **shall clearly display the day, month, and year on which the product was manufactured, or a code indicating such date**. The requirements of this provision shall not apply to products that are offered to consumers free of charge for the purposes of sampling the product.

Federal Trade Commission (FTC)

The FTC Act
Title 15, United States Code, Chapter 2, Subchapter I, Sections 41-58
The FTC Act broadly **prohibits unfair or deceptive acts or practices in or affecting commerce.** The Commission will find deception if, either by the inclusion or exclusion of information, the representation, act, or practice:

- is likely to mislead consumers acting reasonably under the circumstances, and
- is material and consumer injury is likely.

The Commission is given authority under the FTC Act to enact regulations intended to prohibit unfair or deceptive acts or practices.

For more detailed information see FTC's:
FTC Policy Statement Regarding Advertising Substantiation
FTC Policy Statement on Deception

Environmental Marketing Claims
16 CFR 260, Guides for the Use of Environmental Marketing Claims
These guides apply to environmental claims included in labeling, advertising, promotional materials, and all other forms of marketing, whether asserted directly or by implication, through words, symbols, emblems, logos, depictions, product brand names, or through any other means, including marketing through digital or electronic means, such as the Internet or electronic mail. The guides apply to any claim about the environmental attributes of a product, package, or service in connection with the sale, offering for sale, or marketing of such product, package, or service for personal, family, or household use, or for commercial, institutional, or industrial use.

In 2012, the FTC updated the guide sections on general environmental benefit, compostable, degradable, ozone, recyclable, and recycled content claims. It also added new sections on carbon offsets, certifications and seals of approval, free-of claims, non-toxic claims, made with renewable energy claims, and made with renewable materials claims.

For more detailed information, see FTC's:
Environmental Claims: Summary of the Green Guides

Made in the USA Claims
The Federal Trade Commission monitors and enforces "Made in the USA" product claims, including those made on cosmetics. Guidance from the agency requires that products wishing to make an unqualified "Made in the USA" claim must meet the "all" or "virtually all" standard.

States may also enact laws that that govern when a "Made in the USA" claim can be made on a product. For example, under California's revised law "Made in the USA", "Made in America", "U.S.A." or similar labels are allowed even if a product has some foreign components. The labeling is permitted if any foreign component or part does not constitute more than 5% of the final wholesale value of the product or any foreign component or part does not constitute more than 10% of the final wholesale value of the product AND the manufacturer can show that those components cannot be obtained or produced domestically.

Food and Drug Administration (FDA)

In addition to the guidance provided here on U.S. compliance requirements, the FDA offers a number of resources to importers of cosmetic products into the U.S., with translations available in Spanish, French, Chinese, and Korean.

For more information, see FDA's
Information for Cosmetics Importers

Food, Drug, and Cosmetics Act (FD&C Act)

The Federal Food, Drug, and Cosmetic Act (FD&C Act) and subsequent amending statutes are codified into Title 21 Chapter 9 of the United States Code. The purpose of the Act is to ensure that food, drugs, medical devices, and cosmetics are safe and properly labeled. Chapter VI of the Act (21 USC 361 to 363) contains the section on cosmetics and addresses adulterated and misbranded cosmetics.

The introduction or delivery of adulterated or misbranded cosmetics in interstate commerce is a prohibited act under the FD&C Act. A cosmetic product is deemed to be adulterated if it or its container contains a poisonous or deleterious substance which may cause injury when the product is used as directed through labeling or in customary use. Coal-tar hair dye is an exception to the adulteration provisions of the Act provided the product is labeled with the following cautionary statement, "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness."

A cosmetic product is also deemed to be adulterated if it contains any filthy, putrid, or decomposed substance or if it has been prepared, packed, or held under insanitary conditions where it may have become contaminated with filth or where it may have been rendered injurious to health. Additionally, a **cosmetic, excluding hair dyes, may not contain an unsafe color additive**. See Color Additives below.

A cosmetic product is deemed to be misbranded if its labeling is false or misleading and if its container is made, filled, or formed to be misleading. This includes product claims that go

beyond the FDA definition of a cosmetic. In addition, the FDA has issued regulations for cosmetic labeling that can be found at 21 CFR 701, which set forth the specific labeling requirements for cosmetic products. The Regulations require, among other things, that **labels must contain the name and place of business of the manufacturer, packager, or distributor and an accurate statement of quantity (weight, measure, or numerical count).** Note: Metric units are only acceptable as a parenthetical phrase after inch-pound units.

Additionally, the Regulations state that a label may be considered misleading if the name of the product suggests or includes one or more of the ingredient names but not all of the ingredients.

FDA does not require pre-market clearance of cosmetic product claims, nor does the agency have a specific list of "acceptable" vs. "non-acceptable" cosmetic claims. FDA evaluates cosmetic label claims in total context of all wording and images present in labels and collateral promotional literature (including print advertising and websites).

Products will also be deemed to be misbranded if any word, statement, or other information that is required by law is missing or is otherwise not in compliance with placement or prominence as stated in the Regulations. All labeling required by the Regulations must be in English, except for products distributed solely in Puerto Rico or a territory where the predominant language is not English. However, if the label contains any representation in a foreign language then all required information must also be in the foreign language.

For more detailed information, see FDA's
FDA Authority Over Cosmetics

Cosmetic Labeling

Cosmetic labeling is regulated by the FDA under authority of the FD&C Act and the Fair Packaging and Labeling Act (FPLA). **The following information must be displayed on the principal display panel** (the principal display panel is defined for cosmetics at 21 CFR 701.10):

- An identity statement indicating nature and use of the product (see also 21 CFR 701.11)
- An accurate statement of net quantity of contents (see also 21 CFR 701.13)

In addition, **the following must appear on the information panel:**

- Name and place of business – manufacturer, packer, or distributor (see also 21 CFR 701.12)
- Distributor statement if the name is not the manufacturer's
- Material facts (e.g., example for safe use)
- Warning and caution statements
- Ingredients listed in descending order of predominance (see also 21 CFR 701.3 and 701.30)

Note: The phrase “May Contain” can be used for color additives in a line of products that have the same formulation with several different shades, such as lipsticks or eye shadows (see 21 CFR 701.3(g)(1)). Neither the FD&C Act nor the FDA defines the use of the term “natural” or “organic” in cosmetics.

Cosmetic Ingredients

Under the FPLA, ingredients must be listed by their “common or usual names.” Section 701.3(c) of the FDA Regulations prescribes the nomenclature for identifying ingredients in the label declaration. The Regulation lists several sources for identifying the appropriate name for an ingredient, and the sources must be consulted in the order in which they appear in the Regulation. The first source to consult is Section 701.30, which is the Regulation that contains the particular names established by the FDA. Remaining sources are identified in Section 701.3(c)(2). Many of these sources may reflect the names given to these chemical compounds by the industry lead group the International Nomenclature for Cosmetic Ingredients (INCI). FDA does not accept the use of terms from other languages, such as Latin names for the labeling of botanical ingredients or the use or the use of “Aqua” instead of “Water.” FDA does however allow for these terms use in parentheses following the common or usual name in English. “Fragrance” or “Flavor” may be declared as such.

For more detailed information, see FDA’s
Ingredient Names

Cosmetic Warning and Caution Statements

21 CFR 740 Subpart A requires **cosmetics that are hazardous to consumers when misused must be labeled with appropriate warnings and adequate directions for use** if it is not to be deemed misbranded.

21 CFR 740.10 **requires that each ingredient used in a cosmetic product and each finished cosmetic product be adequately substantiated for safety prior to marketing.** Any cosmetic ingredient or product whose safety is not adequately substantiated prior to marketing is considered misbranded **unless it contains the following conspicuous statement on the principal display panel:**

Warning—The safety of this product has not been determined.

This does not constitute an exemption to the adulteration provisions of the Act or to any other requirement in the Act.

21 CFR 740.11 requires **the label of a cosmetic packaged in a self-pressurized container and intended to be expelled from the package under pressure shall bear the following warning**:

Warning – Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120° F. Keep out of reach of children.

The warning may be altered when any of the circumstances below exist.

- In the case of products intended for use by children, the phrase "except under adult supervision" may be added at the end of the last sentence in the warning.
- In the case of products packaged in glass containers, the word "break" may be substituted for the word "puncture" in the warning.
- In the case of a product not expelled as a spray the words "Avoid spraying in eyes" may be deleted from the warning.

In addition to the warning**, the label of a cosmetic packaged in a self-pressurized container in which the propellant consists in whole or in part of a halocarbon or a hydrocarbon shall bear the following warning:**

Warning—Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

The following are exempt from the intentional misuse by inhalation warning above.

- Products expelled in the form of a foam or cream that contain less than 10 percent propellant in the container.
- Products in a container with a physical barrier that prevents escape of the propellant at the time of use.
- Products of a net quantity of contents of less than 2 ounces (oz) that are designed to release a measured amount of product with each valve actuation.
- Products of a net quantity of contents of less than 1/2 oz.

Cosmetics packaged in a self-pressurized container containing or manufactured with a chlorofluorocarbon propellant or other ozone-depleting substance must meet requirements designated by the EPA set forth in 40 CFR 82**.**

Under 21 CFR 740.12, **the label of feminine deodorant spray must have the following warning**:

Caution—For external use only. Spray at least 8 inches from skin. Do not apply to broken, irritated, or itching skin. Persistent, unusual odor or discharge may indicate conditions for which a physician should be consulted. Discontinue use immediately if rash, irritation, or discomfort develops.

In the case of feminine deodorant sprays whose expelled contents do not contain a liquefied gas propellant, such as a halocarbon or hydrocarbon propellant, the statement "Spray at least 8 inches from skin." is not required.

Feminine deodorant spray will be considered misbranded if the label bears the word hygiene, hygienic, or a similar word or any word that represents or suggests that feminine deodorant spray has a medical usefulness.

Under 21 CFR 740.17, the **label of foaming detergent bath products, except for those products that are labeled as intended for use exclusively by adults, shall bear adequate directions for safe use and the following caution**:

Caution—Use only as directed. Excessive use or prolonged exposure may cause irritation to skin and urinary tract. Discontinue use if rash, redness, or itching occurs. Consult your physician if irritation persists. Keep out of reach of children.

In the case of products intended for use by children, the phrase "except under adult supervision" may be added at the end of the last sentence in the caution.

Coal-tar dye containing as an ingredient 4-methoxy-*m*-phenylenediamine (2,4-diaminoanisole) or 4-methoxy-*m*-phenylenediamine sulfate (2,4-diaminoanisole sulfate) must have on the principal display panel of the label and any labeling accompanying the product the following warning:

Warning—Contains an ingredient that can penetrate your skin and has been determined to cause cancer in laboratory animals.

21 CFR 740.19 requires that **sun tanning preparations that do not contain a sunscreen ingredient must display the following warning on the labeling**:

Warning—This product does not contain a sunscreen and does not protect against sunburn. Repeated exposure of unprotected skin while tanning may increase the risk of skin aging, skin cancer, and other harmful effects to the skin even if you do not burn.

Sun tanning preparations include gels, creams, liquids, and other topical products that are intended to provide cosmetic effects on the skin while tanning through exposure to ultraviolet (UV) radiation (e.g., moisturizing or conditioning products) or to give the appearance of a tan by imparting color to the skin through the application of approved color additives (e.g., dihydroxyacetone) without the need for exposure to UV radiation. Sun tanning preparations do not offer protection from UV radiation. Sunscreen and products offering protection from the sun or UV radiation are considered drugs and are subject to FDA drug regulations.

Color Additives

The following regulations relate to color additives used in food, drugs, and cosmetics:
21 CFR 70 Color Additive Regulations
21 CFR 73 Listing of Color Additives Exempt from Certification
21 CFR 74 Listing of Color Additives Subject to Certification
21 CFR 80 Color Additive Certification
21 CFR 81 General Specifications and General Restrictions for Provisional Color Additives for Use in Foods, Drugs, and Cosmetics
21 CFR 82 Listing of Certified Provisionally Listed Colors and Specifications

Color additives for use in cosmetics must meet strict FDA approval, regulations for use, specifications, and restrictions. In addition, certain color additives derived from petroleum are subject to certification by FDA to confirm the composition and purity of each batch of color additives. Color additives obtained primarily from plant, mineral, or animal sources are exempt from certification; however, they must comply with the identity, specifications, uses, restrictions, and labeling requirements stated in the Regulations.

Whether or not a particular color is exempt from certification, the color cannot be used unless it has been approved specifically for the intended use. Specific restrictions include the use of a color additive in the area of the eye, using an external use color additive on lips or areas covered by mucous membrane, and using color additives in injections unless the Regulations allow such uses for that specific color additive.

For more detailed information, see FDA's:
Color Additives and Cosmetics
Summary of Color Additives for Use in the United States in Foods, Drugs, Cosmetics, and Medical Devices

Pending Guidance Documents of Note:
Draft Guidance for Industry: Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended Maximum Level (December 2016)

Prohibited or Restricted Ingredients
FDA regulations 21 CFR 700 Subpart B specifically prohibit or restrict certain ingredients that may be used in cosmetic products that may be injurious to users.

Per 21 CFR 700.11, bithionol has been used in some cosmetic products as an antibacterial agent. Because, when used topically, bithionol can cause persistent photosensitivity in some people, and there is evidence to indicate that it may produce cross-sensitization with other commonly used chemicals such as certain halogenated salicylanilides and hexachlorophene, **Bithionol is a deleterious substance which may render any cosmetic product that contains it injurious to users. Accordingly, any cosmetic containing bithionol is deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act.**

Per 21 CFR 700.13, mercury-containing cosmetic preparations have been represented as skin-bleaching agents**. Any cosmetic product containing mercury will be considered adulterated unless**:

- It contains less than 1 part per million (0.0001 percent) calculated as mercury metal and is unavoidable under conditions of good manufacturing practice, or
- It is a cosmetic intended for use only in the area of the eye, where mercury is used as a preservative and at a level not to exceed 65 parts per million (0.0065 percent), calculated as the metal, and there is no effective and safe nonmercurial substitute preservative available for use in the cosmetic.

Vinyl chloride is a deleterious substance which may render any cosmetic aerosol product that contains it as an ingredient injurious to users. Accordingly, per 21 CFR 700.14, **any cosmetic aerosol product containing vinyl chloride as an ingredient is deemed to be adulterated.** Halogenated salicylanilides (tribromsalan (TBS, 3,4',5-tribromosalicylanilide), dibromsalan (DBS, 4'5-dibromosalicylanilide), metabromsalan (MBS, 3,5-dibromosalicylanilide) and 3,3',4,5'-tetrachlorosalicylanilide (TCSA)), which have been used as antimicrobial agents in certain cosmetics, are potent photosensitizers and cross sensitizers, which can cause disabling skin disorders, and render any cosmetic that contains them injurious to users. Therefore, per 21 CFR 700.15, any **cosmetic product that contains such a halogenated salicylanilide as an ingredient at any level for any purpose is deemed to be adulterated.**

Per 21 CFR 700.16, zirconium-containing complexes are deleterious substances which may render any cosmetic aerosol product that contains it as an ingredient injurious to users. Accordingly, **any cosmetic aerosol product containing zirconium-containing complexes as an ingredient is deemed to be adulterated.**

Per 21 CFR 700.18, chloroform is a deleterious substance which may render any cosmetic product that contains it as an ingredient injurious to users. Any cosmetic product containing chloroform as an ingredient is considered adulterated. Chloroform is not considered to be an ingredient in any cosmetic product where it is found in residual amounts from its use as a processing solvent during manufacture or as a byproduct from the synthesis of an ingredient.

The use of methylene chloride in cosmetic products poses a significant cancer risk to consumers, and its use in cosmetic products may render these products injurious to health. Per 21 CFR 700.19, **any cosmetic product that contains methylene chloride as an ingredient is deemed adulterated.**

Per 21 CFR 700.23, **the use of chlorofluorocarbons in cosmetics as propellants in self-pressurized containers is prohibited.**

Per 21 CFR 700.27, **no cosmetic shall be manufactured from, processed with, or otherwise contain, prohibited cattle materials except as exempted by the Regulation.** Prohibited cattle materials means specified risk materials, small intestine of all cattle except if the distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine, material from non-ambulatory disabled cattle, material from cattle not inspected and passed, or mechanically separated (MS) (Beef).

Per 21 CFR 700.35, **if a cosmetic product contains a sunscreen ingredient for uses other than sun protection and uses the term "sunscreen" or similar sun protection terminology anywhere in its labeling, the term must be qualified by describing the cosmetic benefit provided by the sunscreen ingredient.** The statement must appear prominently and conspicuously at least once in the labeling in conjunction with the term "sunscreen" or other similar sun protection terminology used in the labeling. For example: "Contains a sunscreen—to protect product color." A product that includes the term "sunscreen" in its labeling or in any other way represents or suggests that it is intended to prevent, cure, treat, or mitigate disease or to affect a structure or function of the body is considered a drug and must be compliant with FDA drug regulations.

21 CFR 250.250 sets forth regulations for the use of the antibacterial hexachlorophene in cosmetics. **Hexachlorophene may be used as a preservative in cosmetic products at a level that is no higher than necessary to achieve the intended preservative function and may not be used at levels exceeding 0.1 percent**. It may not be used in cosmetics that are used near or on mucous membranes. Hexachlorophene may only be used in applications where an alternative preservative has not yet been shown to be as effective or where adequate integrity and stability data for the reformulated product are not yet available.

Antibacterial ingredients used as substitutes for hexachlorophene in cosmetic products must be adequately tested for safety prior to marketing. Without safety testing prior to marketing, the product may be considered adulterated and will be deemed misbranded unless it contains a

conspicuous front panel statement that the product has not been adequately tested for safety and may be hazardous.

For more detailed information, see FDA's:
Prohibited and Restricted Ingredients

Microbeads

The Microbead-Free Waters Act of 2015 amends the Food Drug and Cosmetic Act to **ban the sale of rinse-off cosmetics, including toothpaste, that contain intentionally added synthetic microbeads** beginning on January 1, 2018, and to ban manufacturing of these cosmetics beginning on July 1, 2017. A plastic microbead is defined as a solid plastic particle that is less than five millimeters in size and is intended to be used to exfoliate or cleanse the human body. The statutory ban also applies to cosmetics that are non-prescription (over-the-counter or OTC) drugs, although the effective dates for each of the prohibitions applicable to these products is staggered by one year from that applicable to cosmetic products.

Sunscreen

All products that claim to provide Broad Spectrum SPF protection are regulated as sunscreen drug products. This applies to cosmetics and moisturizers labeled with SPF values, as well.

All sunscreens are regulated as drugs in the United States under one of the following processes:

- The new drug approval process described in 21 CFR 314
- The OTC drug monograph process (also known as the OTC Drug Review) described in 21 CFR 330, as supplemented by the Sunscreen Innovation Act

The Sunscreen Innovation Act (SIA) provides a process for the review of safety and effectiveness of nonprescription sunscreen active ingredients. The SIA sets a very specific timeline for the FDA to make a determination on an active ingredient once all data has been made available to the agency. SIA amended the FD&C Act in part by providing new procedures for establishing that nonprescription sunscreen active ingredients or combinations of nonprescription sunscreen active ingredients are generally recognized as safe and effective (GRASE) and not misbranded when used under the conditions specified in a final sunscreen order. Active ingredients that are determined to be GRASE in a final sunscreen order may be used in U.S.-marketed sunscreens without first obtaining an New Drug Application (NDA) or Abbreviated New Drug Application (ANDA).

Labeling Based on Effectiveness Testing

Sunscreens must meet labeling requirements set forth in 21 CFR 201.327. This applies to sunscreen products containing aminobenzoic acid, avobenzone, cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, oxybenzone, padimate O, sulisobenzone, titanium dioxide, trolamine salicylate, or zinc oxide, alone or in combination are covered.

The following must be placed on the principle display panel:

- Statement of Identity
- Effectiveness Claim
    - For products that pass the broad spectrum test, the labeling must state "Broad Spectrum SPF [insert numerical SPF value resulting from testing]".
    - For sunscreen products that do not pass the broad spectrum test, the labeling states "SPF [insert numerical SPF value resulting from testing]".
- Water Resistance Statements – for products that provide water protection according to testing, either 40 or 80 minutes, the labeling shall state "Water Resistant (40 minutes) or (80 minutes) as applicable.
- Indications – only uses that have been established may be included. The following must be included under the heading Uses:
    - [Bullet] Helps prevent sunburn
    - [Bullet] if used as directed with other sun protection measures (see Directions [in bold italic font]), decreases the risk of skin cancer and early skin aging caused by the sun. [This is only applicable to sunscreens with a Broad Spectrum SPF value of 15 or higher according to the testing. Any labeling or promotional materials that suggest or imply that the use, alone, of any sunscreen reduces the risk of or prevents skin cancer or early skin aging will cause the product to be misbranded]
- Warnings – Under the heading Warnings the following must appear:
    - On all sunscreen products:
        - Do not use [bullet] on damaged or broken skin.
        - When using this product [bullet] keep out of eyes. Rinse with water to remove.
        - Stop use and ask a doctor if [bullet] rash occurs
    - On sunscreen products that are broad spectrum with SPF values of at least 2 but less than 15 according to the SPF test:
        - Skin Cancer/Skin Aging Alert [in bold font]; Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not [in bold font] skin cancer or early skin aging. [This must be the first statement under the Warnings heading.]
- Directions
    - For all sunscreen products:
        - [bullet] apply [select one of the following: Liberally or generously] [and, as an option: And evenly] 15 minutes before sun exposure.
        - [bullet] apply to all skin exposed to the sun [optional statement]
        - [bullet] children under 6 months of age: Ask a doctor
    - For sunscreen products with a Broad Spectrum SPF value of 15 or higher according to the tests:
        - [bullet] Sun Protection Measures. [in bold font] Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or

higher and other sun protection measures including: [Bullet] limit time in the sun, especially from 10 a.m.-2 p.m. [bullet] wear long-sleeved shirts, pants, hats, and sunglasses

    - For products that satisfy the water resistance test:
        - [bullet] reapply: [Bullet] after [select one of the following determined by water resistance test: “40 minutes of” or “80 minutes of”] swimming or sweating [bullet] immediately after towel drying [bullet] at least every 2 hours.
    - For products that do not satisfy the water resistance test:
        - [bullet] reapply at least every 2 hours [bullet] use a water resistant sunscreen if swimming or sweating
- Other Information
    - [bullet] protect the product in this container from excessive heat and direct sun

Claims that are considered false and/or misleading on sunscreen products, include, but are not limited to, the following: “Sunblock,” “sweatproof,” and “waterproof.” Use of these or similar claims will cause the product to be considered misbranded.

If the product is a combination of sunscreen and skin protectant, the statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

Tamper-Resistant Packaging

Cosmetic liquid oral hygiene products or products used vaginally that do not have tamper resistant packaging or are not properly labeled are considered adulterated per 21 CFR 700.25.

A tamper-resistant package is one that uses an indicator or barrier to entry that when breached or missing makes it visibly evident to consumers that tampering has occurred. To reduce the likelihood of substitution of a tamper-resistant feature after tampering, the indicator or barrier to entry is required to be distinctive by design (e.g., an aerosol product container) or by the use of an identifying characteristic (e.g., a pattern, name, registered trademark, logo, or picture).

Except for aerosol products, **each retail package of cosmetic liquid oral hygiene products or products used vaginally is required to bear a statement that is prominently placed so that consumers are alerted to the specific tamper-resistant feature of the package**. The labeling statement must be placed so that it will be unaffected if the tamper-resistant feature of the package is breached or missing. If the tamper-resistant feature uses an identifying characteristic to meet the requirement, that characteristic is required to be referred to in the labeling statement. For example, the labeling statement on a bottle with a shrink band could say “For your protection, this bottle has an imprinted seal around the neck.”

Voluntary Cosmetic Registration

FDA's Voluntary Cosmetic Registration Program (VCRP), 21 CFR 710 and 720, is a reporting system for use by manufacturers, packers, and distributors of cosmetic products that are in commercial distribution in the United States. The FDA uses the information from the VCRP to evaluate cosmetic products on the market. Frequency of Use (FOU) data from the VCRP database is also provided by FDA to the independent, industry-funded Expert Panel of the Cosmetic Ingredient Review (CIR) Program. CIR utilizes this information, along with the available scientifically valid literature, to set priorities for those ingredients which the panel will review, ultimately resulting the CIR's review of and assessment of ingredient safety. The VCRP also allows filers to use the secure database as back-up storage for product information. The program is only applicable to products sold to consumers and not for professional products or products that are not for sale, such as hotel samples or gifts.

The VCRP database is not publicly available; however, FDA will provide some information, based upon Freedom of Information Act (FOIA) requests. For example, FDA sometimes receives such requests from consumers or healthcare providers who wish to identify products that do or do not contain certain ingredients. Proprietary business information, however, will not be released pursuant to a FOIA request. Firms may submit written requests for confidentiality of a cosmetic ingredient in accordance with 21 CFR 720.8, which also states how FDA handles such requests.

There are two components to the program, and participant involvement can be in one or both components.

21 CFR 710 outlines the requirements for the voluntary establishment registration portion of the program. Owners or operators of facilities where cosmetics are manufactured and/or packaged can register their establishments. The FDA will assign a registration number to each establishment location.

21 CFR 720 outlines the requirements for the voluntary qualitative cosmetic product ingredient composition statements portion of the program. On the product label, these ingredients will be listed in descending order of predominance. A cosmetic manufacturer, packer, or distributor can file a statement for each product the firm has entered into commercial distribution in the United States. The FDA will assign a Cosmetic Product Ingredient Statement Number (CPIS NO.) to each formulation filed in the VCRP.

For more detailed information See, FDA's:
Voluntary Cosmetic Registration Program

FDA Warning Letters

When the FDA determines that a cosmetic product is in violation of the FD&C Act or an applicable regulation, the FDA has authority to issue a warning letter to the manufacturer or distributor of the product. The warning letter will typically inform the manufacturer of the alleged violations and instruct the manufacturer to detail the corrective action that the

manufacturer intends to take. Usually, the response must be in writing and sent to the respective agency district office, as outlined in the received warning letter, within 15 working days. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure of products and/or injunction against continued manufacturing operations.

For more information, see FDA's:
Warning Letters Related to Cosmetics
FDA's Electronic Reading Room- Warning Letters

FDA Guidance Documents

The FDA has prepared several guidance documents that represent the FDA's interpretation of a policy on issues related to their regulatory mandate. Guidance for industry at the above hyperlink includes cosmetic-specific guidance for good manufacturing practices, nanomaterial safety, labeling, and more. Guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statue, regulations, or both.

United States Department of Agriculture (USDA)

Organic Claims - Organic Foods Production Act of 1990 (OFPA)
Title 7, United States Code, Chapter 94, ORGANIC CERTIFICATION, Sections 6501-6523
The United States Department of Agriculture (USDA) regulates the term organic as it applies to agricultural products through the National Organic Program (NOP) Regulations, 7 CFR Part 205. The NOP regulations include a definition of organic and provide for certification that agricultural ingredients have been produced under conditions that would meet the definition. They also include labeling standards based on the percentage of organic ingredients in a product, including cosmetic products. Any cosmetic product produced in full compliance with the NOP regulations may be labeled as NOP-certified organic and display the USDA organic seal. Any cosmetic, body care product, or personal care product that does not meet the production, handling, processing, labeling, and certification standards may not state, imply, or convey in any way that the product is USDA-certified organic or meets the USDA organic standards.

However, USDA has stipulated that it has no authority over the production and labeling of cosmetics, body care products, and personal care products that are not made up of agricultural ingredients or do not make any claims related to meeting USDA organic standards. Its regulatory oversight for such cosmetic and personal care products does not take jurisdictional precedence over that of FDA for the general compliance with safety and labeling regulatory requirements. "Organic" is not a term regulated by FDA as noted in this discussion. Claims in this area may be subject to FTC jurisdiction.

For more detailed information, see USDA's:
National Organic Program: Cosmetics, Body Care Products, and Personal Care Products

Overview of U.S. State Regulatory Frameworks

A growing number of areas are covered by both state and federal statutes, including consumer protection, employment, and food and drug regulation. State laws give way to stricter federal laws that address the same issue. When the state's Governor signs a bill, it becomes a state law. Once a law has been enacted by a state, it is the responsibility of the appropriate state agency to create the regulations necessary to implement the law within the state. Cross-state issues are considered to be under the jurisdiction of the U.S. Federal Government.

State Regulatory Authorities and Technical Regulations (Mandatory)

In the U.S., some state laws and regulations are enacted which are more stringent than the federal laws. These laws include regulations for products, labeling, packaging, chemical restrictions, etc.

Agency	Scope
State Authorities Responsible for Weights and Measures	Labeling
Toxics in Packaging Clearinghouse (TPCH)	Packaging
California Office of Environmental Health Hazard Assessment (OEHHA)	Toxic chemicals
California Business & Professions Code	Made in the USA claims
California Department of Health	Safe cosmetics
California Department of Food and Agriculture	Organic claims
Florida Department of Business & Professional Regulation, Division of Drug, Devices and Cosmetics	Manufacturer permit
Illinois Department of Public Health	Lead labeling
Louisiana Department of Health and Hospitals	Cosmetic registration and labeling
Minnesota Department of Health	Formaldehyde, triclosan

Packaging and Labeling

Uniform Laws and Regulations (UPLR)

The Uniform Laws and Regulations in the areas of Legal Metrology and Engine Fuel Quality (UPLR), *NIST Handbook 130*, *Uniform Packaging and Labeling Regulation* (*UPLR*), have been adopted into law in 45 of the 50 U.S. states. The purpose of these Regulations is to provide accurate and adequate information as to the identity and the quantity of contents of packages so that purchasers can make price and quantity comparisons.

UPLR requires that consumer packaging (excludes cosmetics as defined by the FDA; includes soap) bear a label specifying the identity of the commodity; the name and place of business of the manufacturer, packer, or distributor; and the net quantity of contents in terms of weight or mass measure, or numerical count in a uniform location upon the principal display panel.

Toxics in Packaging Legislation

This legislation was originally drafted by the Source Reduction Council of the Coalition of Northeastern Governors (CONEG) in 1989. It was developed in an effort to reduce the amount of heavy metals in packaging and packaging components that are sold or distributed throughout the United States. The law is designed to phase out the use and presence of mercury, lead, cadmium, and hexavalent chromium in packaging. The legislation has been successfully adopted by nineteen states.

For more detailed information, see** Toxics in Packaging Clearinghouse **white paper:
Toxics in Packaging Fact Sheet

Chemicals of Concern

Several states, including Oregon, Washington, Vermont, Minnesota, and Maine, **require manufacturers selling children's products that contain a chemical that is included on the state's chemicals of concern list to provide notice to the state prior to sale in that state**. In some cases, the manufacturer must remove or make a substitution for the chemical. The lists are subject to change, including the addition of new chemicals or the removal of listed chemicals, so manufacturers are encouraged to consult the state's reporting rule.

Volatile Organic Compounds

Several states, including California, Illinois, Indiana, Michigan, Ohio, and Utah have issued VOC limitations of consumer products. Products impacted vary by state but may include deodorants, hair mousse, hair shines, hairsprays, hair styling products, nail polish removers, personal fragrance products, shaving creams and gels, and temporary hair color.

State of California

Lead and Other Toxic Substances

California regulates lead and numerous other substances and chemicals through their Safe Drinking Water and Toxic Enforcement Act of 1986, more popularly known as **Proposition 65 or Prop 65** (California Health and Safety Code. Section 25249.6, et seq.) These settlements provide guidelines for suggested limits. Prop 65's List of Hazardous Substances is maintained and updated as new chemicals are identified.

The following warning language **is required on products sold in California if they contain chemicals on the Proposition 65 list** and the level of exposure to the restricted chemical from the product is not within defined safety limits:

WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

On August 30, 2016 the Office of Administrative Law approved amendments to Prop 65—Article 6: Clear and Reasonable Warnings, which modified the warning label that must be used. This becomes effective August 30, 2018, but the new warning can be used before that date.

Businesses that expose individuals to the listed chemical must provide a warning on the product. The warning given must be "clear and reasonable" and must:

- Clearly communicate that the chemical is known to cause cancer, and/or birth defects or other reproductive harm; and
- Effectively reach the person before exposure
    - The consumer product exposure warning must be prominently displayed on a label, labeling, or sign and placed in such a manner that it is likely to be read and understood by an ordinary individual under customary use.

The product warning must contain the following elements:

- A symbol of a black exclamation point in a yellow equilateral triangle with a bold black outline placed to the left of the word WARNING in a size no smaller than the height of the word WARNING.
- The word WARNING in all capital letters and bold print
- The warning statement
    - For exposures to listed carcinogens, the words, “This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.
        - On-product warnings may state: “Cancer - www.P65Warnings.ca.gov.”
    - For exposures to listed reproductive toxicants, the words, “This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.”
        - On-product warnings may state: “Reproductive Harm-www.P65Warnings.ca.gov”
    - For exposures to both listed carcinogens and reproductive toxicants, the words, “This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer, and [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.”

        - On-product warning may state: “Cancer and Reproductive Harm - www.P65Warnings.ca.gov”
    - For exposures to a chemical that is listed as both a carcinogens and a reproductive toxicants, the words, “This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.”
        - On-product warning: “Cancer and Reproductive Harm - www.P65Warnings.ca.gov”

For more detailed California official information on Proposition 65, see:
Office of Environmental Health Hazard Assessment (OEHHA), Proposition 65 in Plain Language,
Prop65 News *from Prop 65 News,*
Notice of Adoption of Article 6: Clear and Reasonable Warnings

California Safe Cosmetics Act
The California Safe Cosmetics Act requires for all cosmetic products sold in California that the manufacturer, packer, and/or distributor named on the product label to provide to the California Safe Cosmetics Program (CSCP) a list of all cosmetic products that contain any ingredients known or suspected to cause cancer or developmental or other reproductive harm. Trace contaminants are not required to be reported. Common cosmetic ingredients that do require reporting are titanium dioxide, retinyl palmitate, and Black 2. The Reportable Ingredients List should be consulted to determine reportable products.

***For More Detailed Information, see California Department of Health’s*:**
California Safe Cosmetics Program

Organic Cosmetics
The California Organic Products Act of 2003 (COPA) requires that cosmetic products sold, labeled, or represented as organic or made with organic ingredients must contain at least 70 percent organically produced ingredients.

Multi-ingredient cosmetic products sold as organic that contain less than 70 percent organically produced ingredients can only identify organic content with one of the following methods.

- Identify each organically produced ingredient in the ingredient statement with the word organic or with an asterisk or other reference mark that is defined below the ingredient statement to indicate the ingredient is organically produced.
- Display the product's percentage of organic contents on the information panel if the organically produced ingredients are identified in the ingredient statement.

The Regulation also stipulates record keeping and registration requirements.

In 2012, Judge Beeler of the U.S. District Court for the Northern District of California ruled that COPA's provisions regarding organic claims for cosmetics are not preempted by the federal Organic Foods Product Act of 1990 (OFPA) because it does not bar state law labeling provisions that do not conflict with OFPA's and National Organic Food Program's provisions.

Made in the USA

California also has laws that govern when a "Made in the USA" claim can be made on a product. While California's law was, at one time, the strictest, a recent law relaxed California's strict "Made in the USA" Law. Under the revised law "Made in the USA", "Made in America", "U.S.A.", or similar labels are allowed even if a product has some foreign components. The labeling is permitted if any foreign component or part does not constitute more than 5 percent of the final wholesale value of the product or any foreign component or part does not constitute more than 10 percent of the final wholesale value of the product AND the manufacturer can show that those components cannot be obtained or produced domestically.

State of Florida

Cosmetic Product Manufacturer Permit

Cosmetics sold in Florida are regulated by the Division of Drugs, Devices and Cosmetics. Any person who manufactures, packages, repackages, labels, or relabels a drug, device, or cosmetic in this state must register such drug, device, or cosmetic biennially. Additionally, a cosmetic manufacturer permit is required for any person that manufactures or repackages cosmetics in this state. A person that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a permit.

State of Illinois

Lead

Public Act 097-0612, The Lead Poisoning Prevention Act

The Act makes it illegal to sell or give away any lead-bearing substance that may be used by the general public, **unless it bears a warning statement as prescribed below, or as prescribed by any other federal regulation.** The statement shall be located in a prominent place on the item or package (16 CFR 1500.121) and shall include at least the following:

> **"WARNING: CONTAINS LEAD. MAY BE HARMFUL IF EATEN OR CHEWED. MAY GENERATE DUST CONTAINING LEAD."**

State of Louisiana

Cosmetics Laws
Packaged cosmetics sold in the state must be registered with the Food and Drug Unit of the Department of Health and Hospitals. Labeling is subject to compliance review as part of the registration.

In addition, a facility engaged in manufacturing, processing, packing, or holding cosmetics must have a valid permit issued by the State Health Officer through the Food and Drug Unit of the Office of Public Health.

Louisiana's Cosmetics Regulation states that hair dye containing coal-tar must have the following caution label as well as adequate instructions for preliminary testing:

> **Caution—this product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.**

Only animal or vegetable dyes and such coal-tar colors as have been certified by the FDA as safe shall be used in, offered for sale for use in, or distributed for use in or on any cosmetic or cosmetic products.

No cosmetic or beauty preparation containing as one of its ingredients estrogenic hormones, any of their chemical derivatives, or any synthetic chemical product possessing properties similar to those of estrogenic hormones may be manufactured, processed, packed, sold, or distributed in Louisiana unless its label bears adequate directions for use and its label bears the number of international units per ounce of each estrogen or synthetic estrogen ingredient.

State of Minnesota

Formaldehyde in Children's Products
Minnesota bans the sale of certain products intended for children aged 8 and under that contain intentionally added formaldehyde or ingredients that degrade into formaldehyde. A children's product is defined as a product primarily designed or intended by a manufacturer to be physically applied to or introduced into a child's body, including any article used as a component of such a product, excluding a food, beverage, dietary supplement, pharmaceutical product or biologic, children's toys (covered under ASTM F963), or a medical device.

Triclosan

Minnesota Statutes Chapter 145 Section 145.945 ban the use of triclosan in products that are used by consumers for sanitizing or hand and body cleansing. The exceptions to this rule are individual products that have received approval from the FDA for consumer use. The ban went into effect January 1, 2017.

Overview of the U.S. Voluntary Standards Framework

The U.S. system of standards development is driven by the private sector. The majority of U.S. standards are voluntary and developed through consensus methods that reflect the needs of producers and manufacturers, users and consumers, and the government. The American National Standards Institute (ANSI) (a non-governmental, not-for-profit organization) coordinates the activities of the standards development community in the U.S. There are hundreds of standards developing organizations in the United States that are responsible for standardization in many different industries and business sectors. The National Institute of Standards and Technology (NIST), a part of the U.S. Department of Commerce, is the national metrology laboratory for the United States. NIST provides the technical measurement infrastructure to support global trade and the commercial measurement system. NIST, through its Standards Coordination Office, advises on and coordinates federal participation in standards setting.

Standards Developing Organizations (SDOs)

ASTM International

100 Barr Harbor Drive
P.O. Box C700
West Conshohocken, PA 19428-2959 USA
Telephone: + 1.610.832.9500
Staff Directory

ASTM International (ASTM) develops and maintains consensus standards and test methods pertaining to a variety of products.

Examples of ASTM standards that may be used for testing cosmetic products include:

ASTM E640	Standard Test Method for Preservatives in Water-Containing Cosmetics
ASTM E2361	Standard Guide for Testing Leave-On Products Using In-Situ Methods
ASTM F719	Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation
WK30352 (Work Item)	New Test Method for XRD Analysis of Cosmetic and Pharmaceutical Talc for Asbestos
WK30024 (Work Item)	New Test Method for Polarized Light Microscopy (PLM) Analysis of Cosmetic and Pharmaceutical Talc for Asbestos

UL Standards

UL Headquarters
333 Pfingsten Road
Northbrook, IL 60062, USA
Telephone: +1. 847.272.8800
Customer Service: +1.877.854.3577
Email: CustomerExperienceCenter@ul.com

UL Standards are used to assess products; test components, materials, systems, and performance; and evaluate environmentally sustainable products, renewable energies, food and water products, recycling systems, and other innovative technologies. UL standards are voluntary unless incorporated by reference into a federal or state regulation or code.

In the US, UL is accredited by the American National Standards Institute (ANSI) as an audited designator. In Canada, UL is accredited by the Standards Council of Canada (SCC) as a nationally recognized Standards Development Organization (SDO) able to develop National Standards of Canada (NSCs).

UL's Standards Technical Panels (STPs) serve as the consensus body for both American National Standards (ANS) and National Standards of Canada (NSC).

UL Standards partners with national standards bodies in countries around the world.

Examples of applicable UL Standards include:

UL 2845	Standard for Sustainability for Personal Care Products
UL 2932A	Standard for Human Health Risk Assessment Process for Personal Care and Cosmetic Products

U.S. Pharmacopeial Convention (USP)

12601 Twinbrook Parkway
Rockville, MD 20852-1790, USA
Telephone: +1.800.227.8772

The USP is a scientific nonprofit organization that sets standards for identity, strength, quality, and purity for medicines, food, and dietary supplements. Although not specifically created for cosmetics, these standards may be used to demonstrate product safety.

USP standards include:

<51>	Antimicrobial Effectiveness Testing
<61>	Microbial Examination of Nonsterile Products: Microbial Enumeration Tests
<62>	Microbial Examination of Nonsterile Products: Tests for Specified Microorganisms

International Standards Organization (ISO)

SO Central Secretariat
BIBC II
Chemin de Blandonnet 8
CP 401
1214 Vernier, Geneva, Switzerland
Telephone: +41 22 749 01 11
Email: central@iso.org

ISO is an independent, non-governmental international organization with a membership of 163 national standards bodies. Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market relevant International Standards.

ISO standards related to cosmetics include the following:

ISO 10130	Cosmetics — Analytical methods — Nitrosamines: Detection and determination of N-nitrosodiethanolamine (NDELA) in cosmetics by HPLC, post-column photolysis and derivatization
ISO 11930	Cosmetics — Microbiology — Evaluation of the antimicrobial protection of a cosmetic product
ISO 12787	Cosmetics — Analytical methods — Validation criteria for analytical results using chromatographic techniques
ISO/TR 14735	Cosmetics — Analytical methods — Nitrosamines: Technical guidance document for minimizing and determining N-nitrosamines in cosmetics
ISO 15819	Cosmetics — Analytical methods — Nitrosamines: Detection and determination of N-nitrosodiethanolamine (NDELA) in cosmetics by HPLC-MS-MS
ISO 16128-1	Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products — Part 1: Definitions for ingredients
ISO 16212	Cosmetics — Microbiology — Enumeration of yeast and mould
ISO/TR 17276	Cosmetics — Analytical approach for screening and quantification methods for heavy metals in cosmetics
ISO 17516	Cosmetics — Microbiology — Microbiological limits
ISO 18415	Cosmetics — Microbiology — Detection of specified and non-specified microorganisms
ISO 18416	Cosmetics — Microbiology — Detection of Candida albicans
ISO/TR 19838	Microbiology — Cosmetics — Guidelines for the application of ISO standards on Cosmetic Microbiology
ISO 21148	Cosmetics — Microbiology — General instructions for microbiological examination

ISO 21149	Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria
ISO 21150	Cosmetics — Microbiology — Detection of Escherichia coli
ISO 22715	Cosmetics — Packaging and labelling
ISO 22716	Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices
ISO 22717	Cosmetics — Microbiology — Detection of Pseudomonas aeruginosa
ISO 22718	Cosmetics — Microbiology — Detection of Staphylococcus aureus
ISO 24442	Cosmetics — Sun protection test methods — In vivo determination of sunscreen UVA protection
ISO 24443	Determination of sunscreen UVA photoprotection in vitro
ISO 24444	Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF)

TESTING AND CERTIFICATION BODIES

Testing

Laboratories

Numerous laboratories test cosmetics to recognized industry standards; some may be accredited.

Testing Procedures

Cosmetics must not contain any harmful organisms. FDA offers a collection of procedures, called Bacteriological Analytical Manual (BAM) for the detection of pathogens in food and cosmetic products, such as, Chapter 23, Microbiological Methods for Cosmetics.

Certification

Products Subject to Consumer Product Safety Rules

Section 102 of the CPSIA **requires every manufacturer or importer of all consumer products that are subject to a consumer product safety rule enforced by the CPSC to issue a certificate** stating that the product complies with the applicable standard, regulation, or ban. The certificate must accompany the product and be furnished to the retailer or distributor. Section 102 also **requires the manufacturers or importers of children's products (age 12 years or younger) to certify that the products comply with all relevant product safety standards by issuing a children's product certificate** supported by tests performed by a CPSC-accepted third-party testing laboratory.

Color Additives

Color additives for use in cosmetics must meet strict FDA approval. In addition, they must meet the requirements for identity, specifications, uses and restrictions, and certifiable color additives (and their corresponding "lakes") must be certified by the FDA. So-called "coal-tar" color additives (i.e., synthetic organic color additives) are subject to batch certification.

For more information, see FDA's:
Color Additives and Cosmetics
Color Additives Permitted for Use in Cosmetics

NSF International
P.O. Box 130140
789 N. Dixboro Road
Ann Arbor, MI 48105, USA
Telephone: +1.734.769.8010
Email: info@nsf.org

NSF is an independent, accredited organization that develops standards and tests and certifies products and systems. It provides auditing, education, and risk management solutions for public health and the environment. Products that comply with all standard requirements can carry an NSF certification mark.

For more information, see NSF's:
Cosmetics
Cosmetic and Personal Care Program

UL Registrar LLC
4 Fork Street, 1st Floor
Mount Pocono, PA 18344 USA
Telephone: +1.800.903.5660
Email: ULRinfo@ul.com

UL Registrar LLC is an ANSI- and ANAB- accredited Conformity Assessment Body, UL Registrar LLC provides independent, accredited third-party manufacturing and process assessments against a defined standard that aims to minimize supply chain risk, help protect brand value, and promote consumer and product safety. UL Registrar is an ANSI-Accredited Certification Scheme for ISO 22716 and provides verification services to cosmetic manufacturers' Good Manufacturing Practices (GMP) required within ISO 22716.

For More Information see UL's:
ISO 22716 Certification whitepaper
Personal Care and Cosmetic Certification Program

RELEVANT U.S. GOVERNMENT AGENCIES

U.S. Consumer Product Safety Commission (CPSC)

4330 East West Highway
Bethesda, MD 20814 USA
Telephone: +1.301.504.7923
Email: http://www.cpsc.gov/About-CPSC/Contact-Information/Contact-Specific-Offices-and-Public-Information/Information-Center/

CPSC Office	Telephone
Office of International Programs and Intergovernmental Affairs	+1.301.504.7071
Office of Compliance and Field Operations	+1.301.504.7915
Deputy Director	+1.301.504.7520
Office of Import Surveillance	+1.301.504.7677

U.S. Customs and Border Protection (CBP)

1300 Pennsylvania Avenue, NW
Washington, D.C. 20229 USA
Telephone: +1.703.526.4200
List of Contacts

For more information see, CBP's:
Importing cosmetics, soap, lotion, shampoo, medical and dental instruments for resale / commercial purposes

Environmental Protection Agency (EPA)

1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Telephone: +1.202.272.0167
List of Contacts

Federal Trade Commission (FTC)

600 Pennsylvania Avenue, NW
Washington, DC 20580
Telephone: +1.202.326.2222
List of Contacts

Food and Drug Administration (FDA)
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
Telephone: +1.888.INFO.FDA
Inquiry Page

COSMETIC INDUSTRY AND MARKET DATA

In the U.S., the cosmetic industry makes an important contribution in developing and providing resources to companies on the manufacturing of cosmetic products and ingredients that are safe for consumers and the environment. This guidance provides resources for additional information to U.S. companies as to how they may comply with U.S. government requirements as well as promoting industry leadership on these issues. Often these initiatives are undertaken with consultation from the U.S. government and other stakeholders, but this does not indicate that these resources are government endorsed.

Industry Trade Associations

A list of industry trade associations can be found on FDA's webpage:
Trade and Professional Associations

Cosmetic Ingredient Review (CIR)
1620 L St. N.W., Suite 1200
Washington D. C. 20036
Phone: (202) 331-0651
Fax: (202) 331-0088
Email: cirinfo@cir-safety.org
Website: www.cir-safety.org

The Cosmetic Ingredient Review (CIR) was established in 1976 by the industry trade association (then the Cosmetic, Toiletry, and Fragrance Association, now the Personal Care Products Council), with the support of the U.S. Food and Drug Administration and the Consumer Federation of America. The CIR studies individual chemical compounds as they are used in cosmetic products and makes recommendations for the industry on the safety and use of these compounds based on a review of the available scientific literature and data.

Although funded by the Council, CIR and the review process are independent from the Council and the cosmetics industry. CIR operates under a set of procedures. General policy and direction are given by a nine-member Steering Committee. The Panel consists of three dermatologists, one of whom is the chair, two chemists, four pharmacologist/toxicologists. Panel non-voting

liaisons include one each from the Personal Care Products Council, U.S. FDA, and Consumer Federation of America.

The FDA observes the activities of CIR, as a non-voting liaison, and may use the findings of CIR in its own safety reviews of cosmetics ingredients.

International Nomenclature for Cosmetics Ingredients (INCI)
c/o Personal Care Products Council
1620 L St. N.W., Suite 1200
Washington D. C. 20036
Phone: (202) 331-0651
Fax: (202) 331-0088
Email: inci@personalcare.org
Website: www.personalcarecouncil.org/public/what-inci

The International Cosmetic Ingredient Nomenclature Committee (INC), sponsored by the Personal Care Products Council, designates the uniform system of names for cosmetics ingredients that are used around the world. In the United States and many other countries, INCI names are referenced by regulations for ingredient labeling of cosmetic products. As part of the process for developing INCI names, the INC oversees the continued development of the INCI nomenclature system, and assures the integrity of the information related to INCI names that is published in the *International Cosmetic Ingredient Dictionary and Handbook*. This systematic nomenclature also serves to move the domestic cosmetics industry and countries that use INCI to harmonization in ingredient names.

For Additional Information, see Personal Care Products Council's publications:

Guideline for Industry: The Stability Testing of Cosmetic Products
This guideline is intended to provide a resource for manufacturers in the development of a stability testing program. It illustrates the industry's current thinking on this topic, and identifies a stability data package that is acceptable for marketing. The guideline outlines key stability parameters for cosmetic products, but leaves sufficient flexibility to encompass the variety of different practical situations that may be encountered due to specific scientific considerations and characteristics of the materials being evaluated. Alternative approaches or variations of these guidelines can be used (e.g., where there is scientific justification or to satisfy requirements within a particular jurisdiction) provided the basic intention of the program is maintained.

International Color Handbook, 4th Edition
The Fourth Edition of the International Color Handbook assists international, regulatory, and technical personnel in choosing a color palette to create the broadest range of cosmetic products while meeting national requirements and analyzes the color additive

regulations for more than 100 countries and compares them to the regulations in the U.S., the European Union, and Japan.

Labeling Manual, 9th Edition
Personal Care Products Council Labeling Manual: A Guide to Cosmetic and OTC Drug Labeling and Advertising, *Ninth Edition*, takes an in-depth look at U.S. regulations for labeling cosmetics, OTC drugs, and professional products. It provides updated and enhanced information on the requirements for cosmetic labeling under the FPLA and the FD&C Act.

Quality Assurance Guidelines
The *Quality Assurance Guidelines* provide approaches that cosmetic manufacturers can use for establishing their good manufacturing practices and quality assurance programs. The *Guidelines* provide a framework for establishing systems and procedures that are necessary to achieve a high level of product quality and avoid problems that could adversely affect the product. *ISO Standard 22716* is included as a companion reference document with these *Guidelines*.

Safety Evaluation Guidelines
Safety Evaluation Guidelines provide manufacturers of cosmetic, toiletry, and fragrance products with guidance in the use of pre-clinical and clinical safety testing as a means to substantiate the safety of both ingredients and finished cosmetic products.

From other U.S. industry associations:

Independent Cosmetic Manufacturers and Distributors (ICMAD)
21925 Field Parkway, Suite 205
Deer Park, IL 60010
Telephone: +1.800.334.2623
Contact Form

CMAD is a nonprofit trade association dedicated to providing programs and services to approximately 700 cosmetic distributors, manufacturers and suppliers.

For additional information, see ICMAD's publications:

The ICMAD Complete Guide to U.S. Cosmetic Regulations and Labeling
This Guide contains information on the cosmetic regulations and labeling requirements, as set forth by the U.S. Food and Drug Administration in both statute and regulation.

The ICMAD Practical Guide to Selling Cosmetics in the U.S.
Selling cosmetics in the United States, the largest market for beauty in the world, has its own set of unique challenges. This guide helps companies familiarize themselves with the rules in the U.S. and make it easier to introduce new products onto the market.

Cosmetic Market Data

Personal Care Products Council
2016 Industry Economic & Social Contributions Study

Personal Care and Cosmetics Products Desk, Office of Materials Industry, U.S. Department of Commerce, International Trade Administration
Industry Focus: Personal Care & Cosmetics Products (Part II)

APPENDIX A: Change Log

May 31, 2017

- The Acknowledgements page was updated to include Craig Weiss from the International Cosmetics Manufacturers and Distributors Association (ICMAD).

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