STC

Your Global Testing,
Inspection & Certification Partner

Cosmetics Testing for US Market

The US Food and Drug Administration (FDA) Definition of Cosmetics

The Federal Food, Drug & 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, etc., for cleansing, beautifying, promoting attractiveness, or altering the appearance" (Section 201(i) of the FD&C Act). Included in this definition are products such as skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, hair perms, hair dyes, and deodorants, as well as any material intended for use as a component of a cosmetic product.

FDA Responsibilities

- Can pursue enforcement action against cosmetic products on the market that are not in compliance with the law, or against firms or individuals who violate the law;
- Collaborate with US Customs to monitor imports: products that do not comply with FDA regulations will be refused entry into the United States;
- Regularly inspect cosmetic companies to ensure that they comply with relative regulations and standards.

Requirements for Cosmetics in the United States

Item	Position	Special Requirements
Name of product	Principal display panel of the outer packaging	Prominent Information
Name and place of manufacturer, packer, or distributor	Label information panel of inner and outer packaging	/
Net quantity of contents	Principal display panel	Indicate the quantity in either U.S. customary units or both U.S. units and metric units
Cosmetics ingredients list	Information panel of the outer packaging	Ingredients with a volume higher than 1% must be listed in descending order; ingredients with a volume less than 1% can be listed arbitrarily; however, all ingredients must be listed by their “common” or “usual” names
Warning statement	Inner and outer packaging	Aerosol products must bear label warnings or cautions prescribed by regulation
Country of origin	Outer packaging	All imported cosmetics should state on the label the English name of the country of origin

Products that Require Particular Attention are

Product Type	US Regulatory Category	Product Type	US Regulatory Category
Antidandruff Shampoo	Over-the-Counter (OTC)	Cleaning Wipes	Cosmetics
Acne Products	Drug	"Decal" Temporary Tattoos	Cosmetics
Hair Products	Drug	Soap	Cosmetics / Ordinary Consumer Goods (by their intended use)
Sunscreen	Over-the-Counter (OTC)	Plastic Artificial Nails	Cosmetics

Prohibited and Restricted Substances

- Bithionol and Chloroform are prohibited
- The use of vinyl chloride and Zirconium-containing complexes is prohibited as an ingredient of aerosol products
- The use of chlorofluorocarbon propellants in cosmetic aerosol products intended for domestic consumption is prohibited
- Color additives are permitted in cosmetics only if the FDA has approved them for the intended use

Restriction Requirements of Microorganisms

- No fecal coliforms, Pseudomonas aeruginosa, or Staphylococcus aureus shall be detected
- Relevant limit requirements for total bacterial count, mold and yeast (FDA)

Safety Assessment

The products and ingredients must undergo sufficient safety assessment and testing before being sold

Special Requirement for California

Products should meet the requirements of CA PROP 65, including restrictions on substances such as lead and cocamide DEA, etc., before being sold in California

One Stop Service

Service	Hazardous Substance Testing	Regulatory Support Documents
Test Items / Documents	• Heavy Metal Test • Microbial Test • Preservative Challenge Test • Phthalates Test • Dioxane Test • Asbestos Test	• Toxicity Risk Assessment • Toxic Substances Control Act (TSCA) Exemption Statement • Safety Data Sheet • Label Ingredient Review

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