I. Welcome to the Industry: Terms, Tools and Tips

Chapter 1

Your Career in Cosmetic Science

Reviewing the key steps to product development and the specialized fields within which scientists work.

key words: careers, contract manufacturers, testing laboratories, quality control, analytical methods, claims support, safety

It is fun to speculate that, at some point in ancient history, an early *Homo sapien* discovered that mud makes the skin feel soft. Thus, the first cosmetic product was born—as was the first cosmetic chemist. Over time, an entire industry evolved to support the development and production of cosmetics. As the industry grew, so did the need for skilled scientists.

Today, the cosmetic industry is a multibillion-dollar enterprise that relies on chemists (and other scientists) to accomplish a multitude of key functions. As a scientist, it is important that you understand not only the part you play in the industry, but also the roles of other scientists and their relationship to you. This chapter reviews the various roles of scientists in the cosmetic industry.

Product Development

Product development or formulating chemists create products designed to meet specific consumer needs. These products include cosmetics (hair- and skincare products) as well as certain over-the-counter (OTC) drugs, such as toothpastes and antiperspirants. To accomplish this task, formulators identify raw materials with the desired functionalities and combine these materials in the proper ratios to yield an acceptable finished product that performs as intended and remains stable.

Knowledge base: Formulating chemists need a solid knowledge of general chemistry, particularly surfactants and emulsification. They must also have a thorough appreciation of the specific chemistry and functionality of the thousands of cosmetic raw materials available. In addition, they often require a specialized knowledge of specific product types, such as aerosols, or drug categories, such as fluoride treatments.

Beyond basic cosmetic science, formulators must be aware of how marketing decisions, cost constraints, manufacturing conditions, and esthetic concerns, such as appearance and odor, can impact product development. A formulator may

develop the world's most effective toothpaste, but if it costs US$10,000 per ounce to produce, looks terrible and tastes even worse, no one will buy it.

Industry Overview Sidebar

To understand the roles of cosmetic scientists, it is important to know what types of companies make up the industry.

Raw material suppliers: Cosmetic products are made up of ingredients supplied by raw material vendors. These vendors use various chemical and physical processes to convert feedstocks, such as petroleum distillates and natural oils, into materials useful in cosmetic products. The thousands of chemical suppliers in this industry make everything from salt to vitamins.

Fragrance vendors: A specialized subcategory of raw material suppliers is fragrance vendors who design and manufacture the fragrances used in cosmetic products.

Finished goods marketers: These companies make finished cosmetic products, such as makeup, shampoo, deodorant, skin lotion and fragrance. They generate product ideas, create and test prototypes, and manufacture finished goods, which are ultimately sold to consumers via retail outlets, salons, wholesale clubs or some form of direct marketing.

Contract manufacturers: Many finished goods marketers do not have the ability or the desire to make all the products they want to sell. Instead, they use the services of contract manufacturers, who specialize in batching and filling finished products.

Testing laboratories: For a variety of reasons, finished goods manufacturers may choose to have their products tested by outside laboratories. For example, it may be easier to have an outside lab conduct skin-moisturization testing because the test protocol requires careful monitoring of human panelists. Similarly, it may be advantageous to have an outside lab run particle-size analysis because the equipment is expensive. Testing labs perform these and many other vital functions in the cosmetic industry.

All of these companies employ a variety of chemists, biologists, engineers and other professionals.

Duties: Formulators are found wherever cosmetic products are created, usually in finished goods companies, contract manufacturers and raw materials suppliers. Formulators typically research useful raw materials (by reviewing trade literature and supplier information), create innovative formulations, prepare actual batches, and test them for functionality and stability. In addition, formulating chemists perform a variety of other functions and are involved in many of the duties performed by the other chemists.

Professional backgrounds: Formulators come from a variety of backgrounds. Some enter this industry straight from college. Typically, product development chemists have a science degree, usually a bachelor's in chemistry. Some have

degrees in biology or related science. A few US colleges offer specialized cosmetic programs (**Table 1.1**).

However, most formulators learn the necessary skills from trade literature and peers, and on the job. The Society of Cosmetic Chemists and the Center for Professional Advancement offer continuing education programs that offer specialized training. Some scientists enter the industry as analytical chemists and transfer to product development. Others come from related fields, such as the paint, coating and textile industries.

Table 1.1. Cosmetic science programs in the United States

United States

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Website: http://www.universities.com/On-Cam-pus/Massachusetts_College_of_Pharmacy__Health_Science_Masters_degree_Industrial_and_Physical_Pharmacy_222942.html
Notes: Massachusetts College of Pharmacy & Health Science—Master's degree—Industrial and Physical Pharmacy and Cosmetic Sciences (MS, PhD).

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Notes: UC's master's of science track in cosmetic science, one of only three such programs in the United States, is available on campus and through a new distance learning option. The college recently launched a novel MS track in drug development in which students focus on the scientific and regulatory aspects of drug discovery/development.

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University Of Puerto Rico
Address
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Notes: This program focuses on the application of pharmaceutical sciences and pharmacy to the study of pharmaceuticals production and distribution, and prepares individuals to manage pharmacies.

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Quality

QC/QA: Quality control/quality assurance (QC/QA) chemists work for finished product manufacturers, raw materials suppliers and contract manufacturers. They ensure that products meet specified company standards by evaluating incoming raw materials and outgoing finished products.

The duties of QC/QA chemists include sampling chemicals from storage containers and performing various analyses, such as for pH, viscosity, IR, solids and percent trace minerals. They can also check labels, calibrate and maintain instruments, and document batch histories.

Since QC/QA chemists are integral to the ongoing manufacturing process, it is critical that they perform their work on a timely, efficient basis to avoid costly production delays. To this end, they must have thorough knowledge and experience in performing tests used to analyze samples.

QC/QA chemists, typically trained as analytical chemists, come from different educational backgrounds and often have varying levels of industrial experience. Because production lines often run around the clock to keep up with demand, this work often involves working in shifts.

Analytical methods development: Many well-staffed companies employ analytical chemists to develop the methods that QC/QA chemists use to test raw materials and finished products. These methods include wet-chemical tests and instrumental analyses, including titration, spectrophotometric analysis, HPLC, gas chromatography and NMR.

During the development of new products with unusual analytical requirements, it is often important that formulators consult with methods development chemists early in the process. Otherwise, it may be very late before the team realizes that no suitable method exists to assay the property.

Methods development chemists must have a solid background in general chemistry and be particularly familiar with instrumental analysis. To develop methods using the latest technology, they must extensively review current developments in analytical chemistry. Many method development chemists have advanced graduate degrees.

Microbiology: Microbiologists are an important technical link in the development and manufacture of cosmetic products. In many ways, they function like QC chemists since they determine whether incoming raw materials and finished products meet company specifications. However, their focus is on whether materials are acceptably free from microbial contamination. Typically, microbiologists sample incoming chemicals and finished batches, then inoculate and conduct plate counts to establish bacteria count.

Beyond quality control, microbiologists can also play a critical role in formulation development. They often help select the optimal preservative system for a product. They are especially important when developing and testing products with proclaimed antimicrobial activity.

Microbiologists require detailed knowledge of the types of microorganisms that may infiltrate cosmetic products as well as conditions of manufacturing, storage and usage that may promote microorganism growth. They must also have detailed knowledge of chemical preservatives and understand the effects raw materials have on preservation systems. For example, nonionic surfactants can inactivate parabenzoic acid derivatives. Microbiologists typically hold degrees in biology, but they may also be chemists or biochemists.

Process Engineering

Chemists (or their engineering cousins, the chemical engineers) who specialize in process engineering solve problems encountered when "scaling up"—the process of transferring a formula from laboratory-sized batches to production-size quantities. Problems often occur during scale up due to drastic differences in the impact of the physical forces that are experienced in the laboratory versus the manufacturing plant.

Process engineers understand how sheer, heat transfer and mixing conditions can impact the quality of finished goods. Their duties include working with chemists to understand the idiosyncrasies of specific formulations while keeping up with current technology of production equipment, such as mixers, pumps, and heating and cooling systems. Process engineers usually hold degrees in chemical or mechanical engineering.

Regulatory

Claims support: Another specialization is substantiating product performance claims. Claims appear on television and radio, and in package copy, print advertising and sales materials, such as brochures and pamphlets. Claims-support scientists must be familiar with the basic properties of cosmetic raw materials and skilled at interpreting claims language.

In addition, claims-support chemists must develop creative testing criteria. In some cases, preestablished test methodology may already be in place, such as standard "regression tests," which quantify skin moisturization. However, other areas are more subjective, such as evaluating shine on hair. Everyone has a preferred method; no universally accepted way to substantiate such claims exists. For this reason, claims support scientists must be knowledgeable of the many tests available. They usually hold degrees in related science areas.

Safety/toxicology: Many companies have specialists who deal with chemical safety or government regulations. For example, environmental specialists ensure that a company and its products comply with current environmental regulations.

Other regulatory chemists make sure that the company complies with employee health, safety rules, labeling requirements and so forth. These scientists are increasingly important as more companies begin to operate globally and must be aware of the regulations in every country where they do business.

Regulatory scientists have degrees in various areas and, typically, a wide range of experience. Because rules and regulations are constantly changing, this job is quite dynamic.

Ingredients Suppliers

Synthesis chemists: Just as finished goods manufacturers hire formulating chemists to create finished products, ingredient suppliers employ synthesis chemists to develop raw materials. These chemists derive chemical reactions that convert coconut oil, petroleum and other feedstocks into functional, salable raw materials.

Synthesis chemists must have a strong background in organic chemistry and be able to creatively develop novel reaction pathways to produce new raw materials.

They should also have a general idea of the properties a finished raw material will have and how they will be economically useful.

Synthesis chemists usually have advanced degrees in specialized areas of organic synthesis, such as esterification reactions or polymerization.

Technical applications development: Once raw materials are developed, the manufacturer must understand their properties to sell them effectively. To this end, many suppliers employ applications chemists that determine how finished-product manufacturers might use a raw material.

Essentially, the duties and background of this job are the same as of the product development chemist, except that these chemists work for an ingredient supplier. Applications chemists may also work across several industries—personal-care, detergents, paints and coatings and so forth.

Technical sales: Raw material suppliers frequently employ chemists on their sales teams because people with technical backgrounds are more likely to suggest meaningful applications. Generally, they communicate more effectively with formulating chemists and their internal technical support.

Technical salespeople perform the same type of tasks as other salespeople, such as meeting with clients, giving presentations and providing support to accounts. While a degree in chemistry or a related field usually suffices, an MBA or sales/marketing experience is often required as well.

Perfumery

Chemists who specialize in formulating fragrances are known as "perfumers." Perfumers have a large palette of organic chemicals with which to formulate fragrances; some perfumes contain as many as 600 materials. Perfumers must have a thorough understanding of the potential interaction between fragrance raw materials and other ingredients to help formulators create finished products with appropriate fragrance characteristics.

In addition to the required technical skills, perfumers must have a highly developed sense of smell and the ability to commit smells to memory. Most fragrance vendors provide perfumers with extensive training programs to cultivate these specialized skills. Many perfumers are employed exclusively by fragrance vendors. However, many finished goods companies employ fragrance coordinators to administrate the process of fragrance selection.

The cosmetic industry is an arena providing a wealth of jobs for scientists. All are critical to the success of product development, manufacturing, sales and, ultimately, the company and the industry.

Published August 1996 *Cosmetics & Toiletries* magazine.

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3. http://sciencecareers.sciencemag.org/career_development/previous_issues/articles/2450/cosmetics_research_reaching_beyond_the_fantasy/(parent)/

Chapter 2

Your Primer of Technical Terms and Chemical Jargon

A "dictionary" of the terms you may encounter in the formulation lab.

key words: product types, ingredients, organizations, process, testing, marketing, regulatory

To function in a scientific environment, you not only need the appropriate technical skills but you must also speak the correct technical language. Every industry has its own jargon that you must understand if you are to succeed. The cosmetic industry is certainly no exception. As an example, imagine yourself as a new formulator. On your very first day at work, you are given a directive in the Can You Decipher This? Sidebar

Obviously, the example we have presented here is exaggerated, but it illustrates the type of technical jargon you must know as a cosmetic chemist. If you aren't familiar with some of the terms in this extremely cryptic message—or if you are relatively new to the industry—you should find this chapter particularly helpful. In it, we try to provide a concise summary of many such terms.

Because we could not possibly define every common term in this industry, we've excluded general chemical terms that you most likely learned in school. For example, *pH* is a very important term in the cosmetic industry, but it is not defined here as you should be familiar with it from your technical training. Conversely, we have included nonchemical terms, such as *consumer perception* and *tress testing* as it is unlikely you encountered them previously.

It is important to realize that we are providing only informal definitions. Our intent is to familiarize you with these terms so you won't be intimidated the first time you encounter them on the job. Therefore, we urge you to review the industry references for further information.

For the sake of our discussion, we've grouped similar terms into eight categories and then arranged them alphabetically within the categories.

Can You Decipher This?

Formulate a product using fatty acids for micelle formation and SLS for foam height. Use only certified dyes that don't violate the Delany clause. If the product has an SPF, make sure it complies with the OTC Monograph, that the ingredient statement uses INCI terminology and that the formula contains no CFCs or VOCs. Furthermore, check the product for compliance with OTC and FDA regulations and ensure claims support is acceptable for FTC and NAD. Also, we may have an OSHA inspection, so prepare an MSDS ASAP.

The Industry

Contract manufacturer (or Private Label): A manufacturer outside your company hired to produce a product for you. Many companies employ contract manufacturers because they don't have the capability to produce all their own products. This practice is particularly common with aerosol products.

Finished Goods manufacturer: A company that creates and markets personal care or cosmetics.

Fragrance house: Supplier of fragrance materials. Very few manufacturers of personal care products actually produce their own fragrances. Instead, they rely on outside vendors to prepare them.

Green: A philosophy in which companies strive to produce personal care products that are environmentally friendly, energy efficient, and contain minimally processed chemicals. Also known as the Natural Movement.

Supplier (or Vendor): A company that sells a chemical raw material, packaging component or other item or services used in the preparation of cosmetic products.

Testing facility: Independent companies that specialize in conducting chemical, physical, and other analytical testing of cosmetic products and raw materials. Additionally, testing companies may conduct safety evaluations, consumer tests, and environmental impact studies.

The Product Types

Aerosol: Product dispensed from a sealed container by a pressurized propellant gas. Hair spray is a good example.

Emulsion: A fine dispersion of one insoluble liquid in another, e.g. oil dispersed in water. Emulsions also usually contain surfactants and/or other stabilizing ingredients that allow the two liquids to form a stable system. Creams and lotions are common emulsions (see "surfactant").

Gel: A semisolid liquid, often clear. Gels are commonly used in hair care, skin care and toothpastes.

Non-aerosol: Product dispensed as a mist from a container fitted with a pump or other user activated dispensing system. Used as an environmentally friendly alternative to aerosols since they lack propellant.

Solution: A mixture of mutually soluble components (alcohol and soluble salts in water, for example).

Stick: A solid form of cosmetic designed to deliver color, fragrance or other active compounds to skin. Most often used for lipsticks, deodorants or antiperspirants.

The Science

Desquamation: The process of sloughing off dead skin cells.

Collagen: A protein responsible for skin strength and elasticity. The breakdown of collagen is the primary cause of wrinkles.

Cortex: Inner layer of the hair shaft responsible for the fiber's strength. Hair coloring products deposit color within the cortex, which helps inhibit removal making it last longer.

Cuticle: Outer layer of the hair composed of keratin protein. This structure is responsible for hair feel, manageability and shine. Hair conditioners primarily work on improving this surface.

Keratin: A class of proteins that are insoluble in water and have a characteristic hardness. Animal hooves and horns, as well as human nails, skin and hair, are composed of keratin.

Static flyaway: Built-up static electrical charges on hair, causing hair to stand out in disarray because individual hair shafts repel each other. Usually occurs in dry weather and low humidity.

Stratum corneum: The outermost layer of skin (and part of the epidermis), comprised primarily of dead cells. Cosmetics are designed to act primarily on this layer.

Substantivity: The tendency of materials to resist being easily removed. For example, some sunscreen lotions are substantive because they form a film on the skin that is relatively water-insoluble. Also, cationic conditioning agents are substantive because they are electrostatically attracted to the hair (see "conditioning agent").

Surface tension: The tendency of a fluid's surface to act as a stretched elastic membrane. Surface tension is the reason a drop of water is spherical.

The Ingredients

Amphoteric surfactant: Characterized by the ability to react as an acid or a base, yielding either H^+ or OH^- ions, depending upon the chemical environment. Particularly known for its mildness (see "surfactant," "zwitterion").

Anionic surfactant: Characterized by a negative charge on its hydrophilic portion. Well-suited to cleansing products due to its ability to disperse oily dirt (see "surfactant").

Cationic surfactant: Characterized by a positive charge on its hydrophilic portion. This charge is attracted to the negatively charged proteins in skin and hair, making this material useful as a conditioning agent (see "conditioning agent," "surfactant").

CFC: Acronym for chlorofluorocarbon. This class of materials, commonly used as aerosol propellants in personal care products until the late 1970s, are claimed to deplete stratospheric ozone.

Chemical feedstock: Raw material used by suppliers to make chemicals. For example, coconut oil is the feedstock for many surfactants.

Colorants: Add color to a product or an applied surface. The federal government strictly regulates the pigments and dyes used in the US cosmetic industry.

Conditioning agent: Improves the feel of hair and skin. For example, hair conditioners leave hair smooth, soft and static-free.

Detergent: A type of surfactant used in cleaning preparations (see "surfactant").

Emollient: When applied to hair or skin, leaves that surface feeling smoother.

Emulsifier: A type of surfactant that allows oil soluble and water soluble components to remain mixed (see "emulsion," "surfactant").

EO/PO: Ethylene oxide/propylene oxide. Added to nonionic surfactants to increase their water solubility. Materials containing these ether linkages are known as ethoxylates and propoxylates (see "nonionic surfactant").

Fatty acid: Long-chain hydrocarbon with a carboxylated end. Basic precursor of many cosmetic raw materials.

FD&C: Abbreviation for Food, Drug and Cosmetic that the US Food and Drug Administration uses to use to classify a category of certified dyes used in personal care products. This system has been modified but is still found on some labels.

Fragrance: Synthetic and/or naturally derived aromatic chemical(s) added to personal care products to produce a specific aroma.

Gelling Agent: Polymeric compound used to create clear, highly thickened or "gelled" personal care products.

Humectant: Class of ingredients that attract and bind water. Typically used for moisturizing and conditioning hair and skin. It is also used to improve stability of formulas exposed to air. Common examples include glycerin and propylene glycol.

Lipid: A class of long-chain hydrocarbons that is insoluble in water. Includes fats, waxes and oils.

Micelle: A (usually) spherical conglomeration of surface active molecules formed in solution. The polar groups on the molecules align toward the water phase and the nonpolar groups tend to point toward the oil or nonpolar phase. This phenomenon allows groups of molecules to form spherical cells. Micelle formation is the basis for most emulsification. **Liposomes** are a form of micelles (see "emulsion," "surfactant").

Moisturizer: Ingredient or product that combats the effects of dryness, e.g. a hair conditioner or skin lotion.

Nonionic surfactant: Characterized by neutral (no net) charge. Immune to the effects of pH, it is a good solubilizing agent and provides flexibility in formulating (see "solubilizer," "surfactant").

Occlusive Agent: Compound that inhibits the evaporation of water from the skin leading to moisturization and an improvement in the look and feel. The most common one is petrolatum.

Oil phase: The oil soluble or nonpolar components of an emulsion (see "emulsion").

Pearlizing agent: Gives a product an opaque, shiny or glossy "pearl" appearance.

Polymer: Long-chain, macromolecules used in a variety of personal care applications including thickening, conditioning, and hair styling.

Preservative: Prevents microbial growth (contamination by bacteria, yeasts, molds, and so on). A good preservation system is critical to ensure a product's stability in use.

Protein: Ingredient based on amino acids that are commonly used in personal care products for conditioning effects.

Quat: Shortened name of quaternary ammonium compound. Characterized by the presence of a nitrogen atom bonded on four sides. Quats are useful because the protonated nitrogen is positively charged, causing it to be attracted to hair and skin where its hydrocarbon backbone can provide conditioning benefits.

Raw material: Chemical used to make personal care products.

Rheological additive: Used to adjust a product's viscosity or flow characteristics.

Silicones: Cosmetic raw materials containing a significant portion of silicone. Typically used for providing surfaces with shine and slickness. Common examples include dimethicone and cyclomethicone.

Solubilizer: A type of surfactant used to disperse an insoluble chemical, like a fragrance oil, in a product (see "surfactant").

Surfactant: A shortened form of "surface active agent." This class of chemicals reduces surface tension; thereby allowing oil and water to form stable mixtures (see "emulsion," "solubilizer").

Suspending agent: Raw material used to immobilize bubbles or large particles in a cosmetic formulation to create a uniformly distributed look.

Viscosity: A measure of a liquid's thickness and flow. Water is typically the benchmark as the lowest viscosity possible.

VOC: Acronym for volatile organic compound. Alcohol and hydrocarbon propellants are prime examples. Recent worldwide legislation has restricted the use of these materials, in attempts to reduce the environmental impact of cosmetics.

Water phase: The water soluble portion of an emulsion (see "emulsion").

The Process

Batching: The preparation of a given quantity of a cosmetic product. It is important to keep track of the products you make by assigning a discrete "batch number" to each batch you make. In the laboratory, a batch can be as small as a few hundred grams; production batches, on the other hand, may be as large as several thousand gallons.

Formula: The chemicals that make up a product, given as their relative proportions (usually expressed as weight-to-weight percentages). Unless the product is made simply by mixing everything at once, the procedure should also be outlined (see "manufacturing procedure").

HLB: Acronym for Hydrophile/Lipophile Balance, a system that helps you select appropriate surfactants for creating stable emulsions.

Table 2.1. A representative sampling of organizations in the cosmetic industry

ACS	American Chemical Society
ASTM	American Standards of Testing Materials (an excellent resource for test methodologies)
COLIPA	European lobbying organization (Belgium)
CTFA	Cosmetic, Toiletry and Fragrance Association (now PCPC)
CTPA	Cosmetic, Toiletry and Perfumery Association (UK)
DOT	US Department of Transportation
EU	European Union
FDA	US Food and Drug Administration (primary regulatory agency for cosmetic industry)
FTC	US Federal Trade Commission
ICMAD	Independent Cosmetic Manufacturers and Distributors
IFSCC	International Federation Societies of Cosmetic Chemists
JCIA	Japanese Cosmetic Industry Association
NAD	National Advertising Division of the Council of Better Business Bureaus
OSHA	US Occupational Safety and Health Administration
PCPC	Personal Care Products Council (Formerly CTFA)
SCC	Society of Cosmetic Chemists (primary professional organization for cosmetic chemists in the United States)
SCS	Society of Cosmetic Scientists (UK)

Lot number: An alphanumeric code that uniquely identifies when and where a specific batch (lot) of material was produced. Lot numbers are assigned to batches of chemical raw materials as well as finished products.

Manufacturing procedure: The "recipe" that tells how to make a product given a specific formula. A good manufacturing procedure includes a description of the equipment required to make the batch, along with step-by-step instructions.

Mill: A piece of equipment used to reduce particle size and achieve a uniform distribution of materials within the finished product.

Mixer: A piece of equipment used to blend components of a formula. Some mixers are simple stirring devices; others provide specialized mixing, such as high shear (see "emulsion").

Pilot plant: Most large companies have facilities for producing large test batches of formulations before manufacturing full scale production batches. A pilot batch may be several to several hundred gallons. Production of these batches should approximate actual production conditions.

QA/QC: Acronym for quality assurance/quality control, the group(s) in a company responsible for testing and ensuring that both incoming components (chemicals and packaging) and finished products meet predetermined specifications.

Scale up: The process of determining the conditions necessary to produce a formula on a larger scale (see "pilot plant").

Shear: The cutting force required to mix components together in cosmetic formulations.

Specification: The range of values acceptable for a specific product characteristic. For example, a product may have a pH specification of 6.0–7. 0. If the product's pH falls outside this range, it is considered "out of spec" and, therefore, unacceptable. Specifications ensure that products and incoming raw materials are the same from batch to batch and remain stable, and that the consumer will not perceive any differences among batches.

Testing

Clinical testing: Generally refers to any test (usually for safety or efficacy) done on human subjects under clinical conditions. With skin care products, often refers to a moisturization study, also known as the Kligman regression study.

Consumer perception: The impression a user has of a product's esthetic and functional characteristics. This test is important because many critical product properties, such as fragrance, are subjective. Thus, technical tests for quality do not anticipate consumer perception (see "consumer testing").

Consumer testing: Any evaluation of consumer perception. Consumer testing, or market research, can help determine if a consumer will like, use, or buy a product (see "consumer perception").

Curl retention testing: A test to determine the efficacy of hair-holding polymers under exaggerated temperature and humidity conditions. Curls are prepared from hair tresses; the hair styling formula is applied to the tresses so a series of linear measurements can determine the amount of curl retained over a specified time.

Draize test: A procedure performed on rabbits to evaluate the eye irritation of cosmetic raw materials and finished products.

Efficacy testing: Evaluates a product's performance.

Flashpoint: A laboratory measurement of the temperature at which a material ignites when exposed to a flame under controlled conditions. This data is important in establishing requirements for shipping and storage of flammable materials.

Foam height testing: Determines ability of a surfactant to lather or produce bubbles (see "surfactant").

Inhalation testing: Establishes the dangers associated with chemicals that enter the body via the lungs. Especially important for aerosol products, which are likely to be inhaled.

LD_{50} testing: Determines the potential ingestion toxicity of a raw material or finished product by finding dose at which 50% of test organisms die.

RIPT: Repeat insult patch testing. Conducted on humans, this test determines the irritation potential of cosmetic products or raw materials.

Salon testing: Evaluations conducted by cosmetologists to determine a product's performance under controlled use conditions.

Stability testing: Series of experiments that determine how a product or raw material changes over time. Establishes an estimated shelf life.

Tensile testing: Special type of hair testing in which fibers are measured for their cross sectional area and pulled to determine the breaking profile.

TEWL: Acronym for transepidermal water loss test; it is used to determine the moisturizing capability of a skin product.

Tress testing: Evaluations of hair care products conducted on hair tresses to simulate actual product usage under controlled laboratory conditions.

Weight study: A parameter that may be evaluated during stability testing. For certain products, it is critical to determine the amount of water (or other solvent) lost or gained through the package since this change may impact formula stability (see "stability testing").

Marketing

Ingredient statement (LOI): The list of ingredients (chemicals) contained in a product. Ingredient statements must appear on cosmetic product packages in the United States, EU and most other countries. The format must meet specific requirements in each.

Packaging: The container (and its component parts) to house a cosmetic product. Packaging types/parts include bottles, caps, pumps, aerosol cans, tubes, boxes, vials and wrappings.

Trade name: Designation a supplier gives a compound.

Regulatory

CIR: Acronym for cosmetic ingredient review. A Personal Care Product Council committee that assesses the safety data related to specific cosmetic raw materials and publishes reports of its findings.

CFR: Acronym for Code of Federal Regulations. A government publication containing the rules and regulations of the United States, including those related to the manufacture and sale of cosmetic products.

Claims: Statements made about the performance or benefits of a personal care product. Establishing support for claims is an important part of new product development.

Cosmetic: (as defined in the US Federal Register) "Articles intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles; except that such term shall not include soap."

Delany Clause: An amendment to the Federal Food, Drug and Cosmetics Act that states that the FDA "shall not approve for use in food any chemical additive found to induce cancer in man, or, after tests, found to induce cancer in animals."

Drug: (as defined in the US Federal Register): "Articles intended for use in the cure, mitigation, treatment, or prevention of disease in man...and articles (other than food) intended to affect the structure or any function of the body of man."

EU: European Union.

FFDCA: Federal Food, Drug & Cosmetic Act

FPLA: Fair Packaging and Labeling Act

INCI: International Nomenclature of Cosmetic Ingredients

MSDS: Material safety data sheet. This literature is designed to alert workers to potentially hazardous characteristics of a compound.

NDA: FDA acronym for "New Drug Application." This expensive, lengthy process to get a chemical approved as a new drug is required if your product makes drug claims and your active ingredient does not fall within current OTC monograph guidelines (see "OTC monograph").

OTC drug: Legal drugs that do not require a prescription and can be sold "over the counter."

OTC monograph: FDA document establishing active ingredients and defining allowable concentrations in OTC drugs (see "OTC drug").

PCPC: Personal Care Products Council. New name for the CTFA.

SPF: Acronym for sun protection factor. A rating that establishes a product's ability to protect the skin from UV radiation.

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Chapter 3

Cosmetic Ingredient Nomenclature

Naming of cosmetic ingredients.

key words: CTFA, INCI System, FDA, Drug, Cosmetic, Personal Care Products Council

No more difficult situation exists than occurs when two or more people cannot communicate because they speak different languages. Confusion, misunderstandings and problems are likely to develop in such a world. Now consider a highly technical world, a world made up of many chemical compounds, with very different properties that are blended together in different combinations and ratios to make products that consumers are going to apply to their person. Now consider the safety of the many compounds and the plethora of formulations containing them. It becomes clear that as scientists, we need to speak a language that clearly communicates the concepts behind our science, in a manner that is clearly understood by our associates, as well as safety professionals and regulators. This information needs to be communicated in a way that is informative and consumer friendly. Now, we begin to define the attributes of the system needed for the personal care industry.

Every student of organic chemistry should be familiar with the IUPAC system of chemical nomenclature. Imagine a world where the full IUPAC names were applied to cosmetic bottles. The names would not only be confusing and incomprehensible, but the required label would simply not fit on the bottle.

In order to understand what is necessary in our industry and to comply with various regulations, it is first necessary to understand the regulatory role and the interrelationships between the different groups participating in the process. One key group is the Food and Drug Administration (FDA). The FDA provides answers to questions critical to our industry on their Web site, *www.fda.com*. Answers to important questions are shown in **Table 3.1**.

Table 3.1. The Food and Drug Administration (FDA)

What does the law say about cosmetic safety and labeling?

The two most important laws pertaining to cosmetics marketed in the United States are the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA).

The FD&C Act prohibits the marketing of adulterated or misbranded cosmetics in interstate commerce. Violations of the Act involving product composition—whether they result from ingredients, contaminants, processing, packaging, or shipping and handling—cause cosmetics to be adulterated and subject to regulatory action. Under the FD&C Act, a cosmetic is adulterated if—

- "it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under conditions of use as are customary and usual" [with an exception made for hair dyes];
- "it consists in whole or in part of any filthy putrid, or decomposed substance";
- "it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health";
- "its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health"; or
- except for hair dyes, "it is, or it bears or contains, a color additive which is unsafe within the meaning of section 721(a)" of the FD&C Act. (FD&C Act, sec. 601)

Improperly labeled or deceptively packaged products are considered misbranded and subject to regulatory action. Under the FD&C Act, a cosmetic is considered misbranded if—

- "its labeling is false or misleading in any particular";
- its label does not include all required information;
- the required information is not adequately prominent and conspicuous;
- "its container is so made, formed, or filled as to be misleading";
- it is a color additive, other than a hair dye, that does not conform to applicable regulations issued under section 721 of the FD&C Act; and
- "its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970." (FD&C Act, sec. 602)

In addition, under the authority of the FPLA, FDA requires an ingredient declaration to enable consumers to make informed purchasing decisions. Cosmetics that fail to comply with the FPLA are considered misbranded under the FD&C Act.

It is important to understand that Congress passes the laws that govern the United States. To put those laws into effect, Congress authorizes certain government agencies, including FDA, to create and enforce regulations, but only as authorized under the law. A change in FDA's statutory authority over cosmetics would require Congress to change the law.

Does FDA approve cosmetics before they go on the market?

FDA's legal authority over cosmetics is different from other products regulated by the agency, such as drugs, biologics, and medical devices. Cosmetic products and ingredients are not subject to FDA premarket approval authority, with the exception of color additives. However, FDA may pursue enforcement action against violative products, or against firms or individuals who violate the law.

Who is responsible for substantiating the safety of cosmetics?

Cosmetic firms are responsible for substantiating the safety of their products and ingredients before marketing. Failure to adequately substantiate the safety of a cosmetic product or its ingredients prior to marketing causes the product to be misbranded unless the following warning statement appears conspicuously on the principal display panel of the product's label:

"Warning—The safety of this product has not been determined."
(21 CFR 740.10)

In addition, regulations prohibit or restrict the use of several ingredients in cosmetic products and require warning statements on the labels of certain types of cosmetics.

> In general, except for color additives and those ingredients which are prohibited or restricted from use in cosmetics by regulation, a manufacturer may use any ingredient in the formulation of a cosmetic provided that the ingredient and the finished cosmetic are safe, the product is properly labeled, and the use of the ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws that FDA enforces.

Can FDA order the recall of a hazardous cosmetic from the market?

Recalls of cosmetics are voluntary actions taken by manufacturers or distributors to remove from the marketplace products that represent a hazard or gross deception, or that are somehow defective. FDA categorizes a firm's action

Table 3.1. continued

as a recall (as opposed to a market withdrawal) when it determines that the product hazard or defect represents a violation of the FD&C Act.

FDA is not authorized to require recalls of cosmetics but does monitor companies that conduct a product recall and may request a product recall if the firm is not willing to remove dangerous products from the market without FDA's written request. Recalls are addressed in Title 21 of the Code of Federal Regulations (CFR), sections 7.40 through 7.59.

What actions can FDA take against firms that market adulterated or misbranded cosmetics?

FDA may take regulatory action if it has information to support that a cosmetic is adulterated or misbranded. The agency can pursue action through the Department of Justice in the federal court system to remove adulterated and misbranded cosmetics from the market. To prevent further shipment of an adulterated or misbranded product, the agency may request a federal district court to issue a restraining order against the manufacturer or distributor of the violative cosmetic. Violative cosmetics may be subject to seizure. FDA also may initiate criminal action against a person violating the law.

In addition, FDA works closely with the US Customs Service to monitor imports. Under section 801(a) of the FD&C Act, imported cosmetics are subject to review by FDA at the time of entry through US Customs. Products that do not comply with FDA laws and regulations are subject to refusal of admission into the United States. Violative products must be brought into compliance (if feasible), destroyed, or re-exported.

FDA takes regulatory action based upon agency priorities, consistent with public health concerns and available resources.

Can FDA inspect cosmetic manufacturers?

FDA can and does inspect cosmetic manufacturing facilities to assure cosmetic product safety and determine whether cosmetics are adulterated or misbranded under the FD&C Act or FPLA.

Does FDA test cosmetics?

The FD&C Act does not subject cosmetics to FDA pre-market approval in order to be marketed legally. However, FDA collects samples for examination and analysis as part of its plant inspections, import inspections, and follow-up to complaints of adverse reactions. FDA may also conduct research on cosmetic products and ingredients to address safety concerns.

The agency does not function as a private testing laboratory, and in order to avoid even the perception of conflict of interest, does not recommend private laboratories to consumers or manufacturers for sample analysis. Testing laboratories are listed in your telephone directory.

Must cosmetic manufacturers register with FDA?

Manufacturers are not required to register their cosmetic establishments, file data on ingredients, or report cosmetic-related injuries to FDA. However, companies are encouraged to register their establishments and file Cosmetic Product Ingredient Statements with FDA's Voluntary Cosmetic Registration Program (VCRP).

Is It a Cosmetic, a Drug, or Both?

The legal difference between a cosmetic and a drug is determined by a product's intended use. Different laws and regulations apply to each type of product. Firms sometimes violate the law by marketing a cosmetic with a drug claim, or by marketing a drug as if it were a cosmetic, without adhering to requirements for drugs.

How does the law define a cosmetic?

The Food, Drug, and Cosmetic Act (FD&C Act) defines cosmetics by their intended use, 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)]. Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colors, toothpastes, and deodorants, as well as any material intended for use as a component of a cosmetic product.

How does the law define a drug?

The FD&C Act defines drugs by their intended use, as "(A) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and (B) articles (other than food) intended to affect the structure or any function of the body of man or other animals" [FD&C Act, sec. 201(g)(1)].

How can a product be both a cosmetic and a drug?

Some products meet the definitions of both cosmetics and drugs. This intersection 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

Table 3.1. continued

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 the requirements for both cosmetics and drugs.

What about "cosmeceuticals"?

The FD&C Act does not recognize any such category as "cosmeceuticals." A product can be a drug, a cosmetic, or a combination of both, but the term "cosmeceutical" has no meaning under the law.

How is a product's intended use established?

Intended use may be established in a number of ways. Among them are:

- **Claims stated on the product labeling, in advertising, on the Internet, or in other promotional materials.** Certain claims may cause a product to be considered a drug, even if the product is marketed as if it were a cosmetic. Such claims establish the product as a drug because the intended use is to treat or prevent disease or otherwise affect the structure or functions of the human body. Some examples are claims that products will restore hair growth, reduce cellulite, treat varicose veins, or revitalize cells.
- **Consumer perception, which may be established through the product's reputation.** For products in this position the consumer would be asked why she is buying it and what she expects it to do.
- **Ingredients that may cause a product to be considered a drug because they have a well known (to the public and industry) therapeutic use.** An example is fluoride in toothpaste.

This principle also holds true for essential oils in fragrance products. A fragrance marketed for promoting attractiveness is a cosmetic. But a fragrance marketed with certain "aromatherapy" claims, such as assertions that the scent will help the consumer sleep or quit smoking, meets the definition of a drug because of its intended use.

How are the laws and regulations different for cosmetics and drugs?

The following information is not a complete treatment of cosmetic or drug laws and regulations. It is intended only to alert you to some important differences between the laws and regulations for cosmetics and drugs in the areas of approval, good manufacturing practice, registration, and labeling. You should direct questions regarding laws and regulations for drugs to CDER.

How approval requirements are different

FDA does not have a premarket approval system for cosmetic products or ingredients, with the important exception of color additives. Drugs, however, are subject to FDA approval. Generally, drugs must either receive premarket approval by FDA or conform to final regulations specifying conditions whereby they are generally recognized as safe and effective, and not misbranded. Currently, certain—but not all—over-the-counter (OTC) drugs (that is, non-prescription drugs) that were marketed before the beginning of the OTC Drug Review (May 11, 1972) may be marketed without specific approval pending publication of final regulations under the ongoing OTC Drug Review. Once a regulation covering a specific class of OTC drugs is final, those drugs must either

- Be the subject of an approved **New Drug Application (NDA)** [FD&C Act, sec. 505(a) and (b)], or
- Comply with the appropriate **monograph**, or rule, for an OTC drug.

What do these terms mean?

An **NDA** is the vehicle through which drug sponsors formally propose that FDA approve a new pharmaceutical for sale and marketing in the United States. FDA only approves an NDA after determining, for example, that the data are adequate to show the drug's safety and effectiveness for its proposed use and that its benefits outweigh the risks. The NDA system is also used for new ingredients entering the OTC marketplace for the first time. For example, the newer OTC products (previously available only by prescription) are first approved through the NDA system and their "switch" to OTC status is approved via the NDA system.

FDA has published **monographs**, or rules, for a number of OTC drug categories. These monographs, which are published in the Federal Register, state requirements for categories of non-prescription drugs, such as what ingredients may be used and for what intended use. Among the many non-prescription drug categories covered by OTC monographs are

- acne medications
- treatments for dandruff, seborrheic dermatitis, and psoriasis
- sunscreens

A note on "new drugs"

Despite the word "new," a "new drug" may have been in use for many years. If a product is intended for use as a drug, no matter how ancient or "traditional" its use may be, once the agency has made a final determination on the status of an OTC drug product it must have an approved NDA or comply with the

Table 3.1. continued

appropriate OTC monograph to be marketed legally in interstate commerce. Certain OTC drugs may remain on the market without NDA approval pending final regulations covering the appropriate class of drugs.

Where to learn more about NDAs and OTC monographs

If you have questions about NDAs and OTC monographs, you should address them to CDER. The CDER Handbook provides an introduction to the drug approval and OTC monograph processes. Other resources, also available on CDER's Web site, provide additional information on these subjects.

How good manufacturing practice requirements are different

Good manufacturing practice (GMP) is an important factor in assuring that your cosmetic products are neither adulterated nor misbranded. However, no regulations set forth specific GMP requirements for cosmetics. In contrast, the law requires strict adherence to GMP requirements for drugs, and there are regulations specifying minimum current GMP requirements for drugs [Title 21 of the Code of Federal Regulations (CFR), parts 210 and 211]. Failure to follow GMP requirements causes a drug to be adulterated [FD&C Act, sec. 501(a)(2)(B)].

How registration requirements are different

FDA maintains the Voluntary Cosmetic Registration Program, or VCRP, for cosmetic establishments and formulations [21 CFR 710 and 720]. As its name indicates, this program is voluntary. In contrast, it is mandatory for drug firms to register their establishments and list their drug products with FDA [FD&C Act, sec. 510; 21 CFR 207].

How labeling requirements are different

A cosmetic product must be labeled according to cosmetic labeling regulations. See the Cosmetic Labeling Manual for guidance on cosmetic labeling. OTC drugs must be labeled according to OTC drug regulations, including the "Drug Facts" labeling, as described in 21 CFR 201.63. Combination OTC drug/cosmetic products must have combination OTC drug/cosmetic labeling. For example, the drug ingredients must be listed alphabetically as "Active Ingredients," followed by cosmetic ingredients, listed in order of predominance as "Inactive Ingredients."

The Personal Care Products Council

In order to develop a system that meets the above criteria, The Personal Care Products Council has been established by our industry to work with the FDA (Food and Drug Administration), members of our industry, consumers and other interested individuals. An understanding of the function of the FDA, The Personal Care Products Council and the responsibility of cosmetic companies, and raw material suppliers is key to understanding our industry.

Table 3.2 outlines the function of the Personal Care Products Council and is taken from their Web site, www.ctfa.org.

Table 3.2. The Personal Care Products Council[1]

The following information taken from www.ctfa.org is important to the understanding of the function of this key organization.

> The Personal Care Products Council (formerly the Cosmetic, Toiletry and Fragrance Association) is the leading national trade association for the cosmetic and personal care products industry and represents the most innovative names in beauty today.
>
> For more than 600 member companies, we are the voice on scientific, legal, regulatory, legislative and international issues for the personal care product industry. We are a leading and trusted source of information for and about the industry and a vocal advocate for consumer safety and continued access to new, innovative products.
>
> ### About the Personal Care Products Industry
>
> Every day, millions of consumers around the world rely on personal care products to live better, healthier lives. From moisturizers, lipsticks and fragrances to sunscreens, soaps and anti-cavity toothpastes, these products are essential to today's consumer lifestyles. The personal care products industry is a global industry with more than $250 billion in annual retail sales.
>
> ### Committed to Safety and Science
>
> Product safety is the top priority of the personal care products industry. We work diligently with our members to maintain the highest standards of safety rooted in science and cutting-edge research. Through self-regulation, the Council works to uphold and often surpass the most stringent US consumer product safety standards. The Council has adopted a Consumer Commitment Code to formalize many existing product safety practices and to demonstrate its members' commitment to safety. The linchpin of our

Table 3.2. continued

self-regulatory programs is the Cosmetic Ingredient Review (CIR) Expert Panel, an independent, nonprofit panel of world-renowned scientists and physicians established in 1976 to assess the safety of ingredients used in cosmetics in the United States with the support of the US Food and Drug Administration (FDA) and the Consumer Federation of America. Recognizing the enormous expense and inefficiency of duplicate safety testing on ingredients by member companies, the industry gathers worldwide published and unpublished safety data for review by the independent expert panel.

Providing In-Depth Information

We recognize and value our position as a trusted, relied upon source of information about the global beauty industry. On any given day, beauty, trade and mainstream media depend on our organization for credible, accurate information about the personal care products industry and its products. For example, our website, **www.cosmeticsinfo.org**, provides in-depth information on ingredient safety and the safety assessment processes used on cosmetics and personal care product ingredients.

Advocating for Consumer Safety

We are an active, vocal advocate for consumer safety. We work with the US FDA and federal, state, and local leaders to ensure quality and safety standards that protect the health of consumers and the environment. Our goal is to strengthen voluntary industry self-regulatory programs and promote uniform national regulatory standards.

Pursuing Harmonized Global Regulatory Standards

The Council works to harmonize global regulatory practices for consumer products; to eliminate trade barriers; and to ensure a level playing field for all our member companies while instilling consumer confidence in product safety.

The Mission—INCI Names

In the early 1970s, the US cosmetics industry became concerned about government regulation. To demonstrate its capability for self-regulation, it instituted programs to encourage voluntary registration of cosmetic formulations and to scientifically review the safety and efficacy of cosmetic ingredients. Naming of cosmetic ingredients is one of the most important functions of the Personal Care Products Council. **Table 3.3** outlines some of the rules for nomenclature.

Table 3.3. Inventory of Ingredients—Nomenclature Conventions

Conventions used for establishing INCI names are as follows:

1. In order to facilitate use and clarity, INCI names have been designed to require a minimum of punctuation and capitalization.
2. Wherever new nomenclature has been adopted, every effort has been made to use the shortest name consistent with these rules.
3. Simple chemical names are used wherever possible.
4. Recognized chemical abbreviations are used where applicable. A list of the abbreviations used in the Inventory may be found under the section "Abbreviations".
5. Traditional stems are retained as combining forms when consistent with other systems (see rule 17).
6. Abbreviations are utilized for simplifying the nomenclature of families of complex ingredients when applicable (see abbreviation list under the section "Abbreviations").
7. Compounds that are related or are similar to materials described in recognized sources are named, whenever possible, by analogy to the listed names.
8. Singly substituted derivatives do not usually include the prefix "mono". This term is used only when required to prevent ambiguity. The absence of a suitable prefix implies "mono", e.g. Glyceryl stearate.
9. The term "Glyceride" has been utilized to describe a monoglyceride. Mixtures of mono-, di- and triglycerides are referred to as "Glycerides". Triglycerides are assigned specific nomenclature, e.g. Tristearin.
10. Multiple substitution is routinely described with the appropriate prefix such as "di-", "tri-" or "tetra-", e.g. Glyceryl distearate.
11. Names of ingredients, other than colors, that contain terminal numbers are generally hyphenated. Derivatives of hyphenated materials retain the original hyphen, e.g. Laureth-3, Laureth-3 phosphate.
12. Hydration states are not usually expressed.
13. Straight-chain alkyl groups are described by their common stem names (see rule 17).
14. Materials containing mixtures of even-carbon chain length fractions are named by the appropriate commonly used fatty stem term, e.g. Cetearyl alcohol (C16 and C18). Materials containing mixtures of even- and odd-carbon chain length fractions are designated by alternative nomenclature, e.g. C12-15 alcohols (C12, C13, C14 and C15).
15. Branched-chain alkyl groups are usually described by the prefix "iso" followed by the common stem name for the comparable straight-chain group (e.g. Isostearyl alcohol, Isocetyl alcohol)—see also rule 17. The major exception to this rule is the nomenclature for the 2-alkyl of Guerbet alcohols. These are named by standard chemical rules (e.g., Ethylhexanol, Octydodecanol, Decyltetradecanol). Derivatives are named accordingly (e.g., Ethylhexyl myristate, Cetyl ethylhexanoate, Diethylhexylamine, Triethylhexanoin, Butyloctanoic acid).

*European Commission—Enterprise and Industry Directorate General Consumer goods—Cosmetics, 24/02/06

Table 3.3. continued

16. The following table has been included to clarify the nomenclature for derivatives of caproic, caprylic and capric acids.

Chain length	*Stem name*	*Acid*	*Ester*
C6	Capro	Caproic	Caproate
C8	Capryl	Caprylic	Caprylate
C10	Capr	Capric	Caprate

Chain length	*Acyl*	*Alkyl*	*Ampho*
C6	Caprooyl	Caproyl	Caproo
C8	Capryloyl	Caprylyl	Caprylo
C10	Caproyl	Capryl	Capro

17. The following table describes the nomenclature applied to straight-chain acids and alcohols. Branched-chain acids and alcohols utilize the names listed in this table preceded by the term "iso" (e.g., Isostearic acid). Guerbet alcohols, however, are designated by specific names (e.g., Octyldodecanol). (See also rule 15).

Saturated:

	Acid	*Alcohol*
C6	Caproic	Hexyl
C7	Heptanoic	Heptyl
C8	Caprylic	Caprylyl
C9	Pelargonic	Nnyl
C10	Capric	Decyl
C11	Undecanoic	Undecyl
C12	Lauric	Lauryl
C13	Tridecanoic	Tridecyl
C14	Myristic	Myristil
C15	Pentadecanoic	Pentadecyl
C16	Palmitic	Cetyl
C17	Margaric	Heptadecyl
C18	Stearic	Stearyl
C20	Arachidic	Arachidyl
C22	Behenic	Behenyl

Unsaturated:

C11	Undecylenic	Undecylenyl
C16	Palmitoleic	Palmitoeyl
C18	Oleic	Oleyl
C18	Linoleic	Linoleyl
C18	Linolenic	Linolenyl
C20	Arachidonic	Arachidonyl
C22	Cetoleic	Cetoleyl
C22	Erucic	Erucyl

18. The nomenclature for ingredients consisting of mixtures of similar materials (e.g., fatty acids, fatty alcohols) is determined on the basis of the chemical identity of the raw material as purchased. Mixtures that reflect the original

distribution of components due to their natural source (e.g., coconut) are named utilizing the source stem (e.g., coconut alcohol). If the original natural distribution has been significantly cut or enriched, the mixture is named on the basis of the predominant component.

19. Names of lanolin derivatives usually contain the stem “lan”, e.g.. Laneth-60.
20. Because of the existing widespread use of these denominations, alkanolamides are named from the parent alkyl amide and the appropriate abbreviation for the amine used, e.g., Cocamide MEA.
21. The dimethyl term is omitted and is assumed in all alkyl dimethyl amine oxide names (e.g., Stearamine oxide). Tertiary amine oxides with different substituent groups are named completely (e.g., Dihydroxyethyl stearamine oxide).
22. Quaternary, ammonium salts usually have the suffix “-ium” in the stem of the cation. The term “monium” describes a monomethyl-substituted quaternary nitrogen; “dimonium” describes a dimethyl-subsituted quaternary nitrogen; “trimonium” describes a trimethyl-substituted quaternary nitrogen.
23. The terms quaternium/polyquaternium are used to describe complex quaternary ammonium salts that do not have a common name or that cannot be named by analogy to established names (e.g., Quaternium-82, Polyquaternium-20).
24. The term “ampho” has been used as a combining term in the nomenclature for amphoteric surfactants derived from imidazoline intermediates. In naming these compounds, this stem is combined with the appropriate stem names for the substituent groupings (e.g., Sodium Cocoamphoacetate).
25. Common fatty stem terms are used to designate the alkyl portion of alkyl imidazoline compounds (e.g., Lauryl Hydroxyethyl Imidazoline) even though one carbon atom of the fatty radical becomes a member of the heterocyclic ring during the materials’ manufacture.
26. Biological materials are named by specific terms (e.g., Hyaluronic Acid, Hydrogenated Menhaden Oil) when the material has been isolated, purified and chemically characterized. Alternative nomenclature for biologicals is utilized to name materials in accordance with the extent of their processing. They may have INCI names based on: (a) the Latin name of the genus, or (b) primarily on designations from Pharmacopoeias, followed by the part used if pertinent, and the type of preparation if pertinent (e.g., extract, oil, powder, etc.). For mammalian derived ingredients, usually (c) the INCI names are based on the English name of the part used, if pertinent (e.g., connective tissue, spleen, stomach, etc.) and the type of preparation, if pertinent (e.g. extract, oil).

    Examples of INCI names for biologicals are (a) Brevoortia Oil; (b) Faex Extract; (c) Connective Tissue Extract.
27. Cosmetic colorants have INCI names according to the nomenclature used in Annex IV to Directive 76/768/EEC.
28. Hair dye ingredients are named according to chemical structure. In the event that chemical names are very complex, a colour/number combination is used prefixed by the letters “‘HC”.
29. Denatured alcohols are designated by the INCI name “Alcohol denat.”. Alcohol denat. is ethyl alcohol that is denatured with one or more denaturing agents in accordance with the national legislation of each Community Member State.

Table 3.3. continued

30. Materials derived from plants are known as botanicals. In general, these ingredients have not undergone chemical modifications and include plant derived ingredients such as extracts, juices, waters, distillates, powders, oils, unsaponifiables, etc. They have INCI names based on the international Linné designated nomenclature of the genus and the species, followed by the plant part, if pertinent or applicable (e.g., leaf, fruit, bark, etc.), and the type of preparation (e.g., extract, oil, powder, etc.). Chemical derivatives of botanicals follow the nomenclature rules for chemicals (e.g., Cocoglyderides, Hydrogenated Castor Oil, Hydrogenated Palm Acid, Olive Acid, Palm Alcohol, Soyamide DEA, Sulfated Olive Oil, etc.).

    The following references are used to establish the Linné-derived for botanicals: (a) The primary referece is Penso, G., *Index Plantarum Medicinalium Totius Mundi Eorumque Synonymorum*, O.E.M.F. Milano (1983—ISBN 88-7076-027-8. (b) When the genus and species is not identified in the text cited in (a), a variety of secondary sources are utilized including the following, in order of priority: (1) Steinmetz, E.F., *Codex vegetabilis*, Amsterdam (1957); (2) Hoppe, H.A., *Drogenkunde*, 8th Edition, Walter de Gruyter, Berlin, Volume 1 (1957—ISBN 3-11-00-8), Volume 2 (1977 – ISBN 3-11-006660-2); (3) Mabberley, D.J., *The Plant Book—A portable dictionary of higher plants*, Cambridge 1992—ISBN N° 0-521-34060-8; (4) Hoppe H.A., Levring T., Tnaka Y., Marine Algae in Pharmaceutical Science, Walter de Gruyter, Berlin, New York, 1979.

31. Name/number combinations are used as INCI names for cosmetic ingredients only where the complexity and/or similarity of ingredients precludes assignment of reasonable nomenclature by any other means. In all cases where arbitrary numbers are used, these numbers are preceded by names suggestive of the structure or the composition of the material. Each name/number combination represents a specific ingredient that is listed in the Inventory. The following name/number series of combinations have been used:

    (a) Benzophenone
    This term is used for all benzophenon derivatives
    (e.g., Benzophenone-2).
    (b) HC color
    See rule 28.
    (c) Quaternium/Polyquaternium
    See rule 23.
    (d) Hydrofluorocarbon/Hydrochlorofluorocarbon
    These terms are used for hydrohalocarbon aerosol propellants
    (e.g.Hydrofluorocarbon 152a, Hydrochloroflurocarbon 142b).
    (e) Polysilicone
    common names or established conventions for silicone compounds (e.g., Poylsilicone-1)
    (f) Polyacrylate
    see rule 49.
    (g) Polyester-
    see rule 49.
    (h) Polyether-
    see rule 49.
    (i) Polyurethane-
    see rule 49.

32. Commercial raw materials are often deliberate mixtures of several components. The mixtures do not appear as such and must be identified by listing the individual components (e.g., Kathon CG: Aqua, Chloromethylisothiazolinone, Methylisothiazolinone, Magnesium chloride, Magnesium nitrate).
33. The INCI names for extracts represent the "material extracted" and do not include reference to the extracting solvents and/or other diluents that may be present in these materials.
34. Solvents and/or diluents contained in commercially available raw materials such as surfactants, polymers and resins are not normally identified as part of the INCI name.
35. Polyethylene glycol (polyoxy-1, 2-ethanediyl) is abbreviated to the acronym "PEG".

    Polyethylene glycol homopolymers are named as PEG-X, where X is the average number of ethylene oxide monomer units, e.g., PEG-10.
    Ethoxylated alcohols are named by combining the conventional alcoholic stem name with the suffix "eth" followed by the average number of ethylene oxide monomer units, e.g. Laureth-10.

    Esters of polyethylene glycol homopolymers are named as PEG derivatives, e.g., PEG-10 stearate.

    Other ethoxylated substances are named accordingly, e.g., PEG-6 cocamide.

    Because names based on the approximate molecular weight of the ethylene oxide polymer are also in common use, the following table is provided to allow easy conversion between the two systems:

Approximate Molecular Weight	Average Number of Monomer Units
100	2
200	4
300	6
400	8
450	9
500	10
600	12
1000	20
1540	32
1800	36
2000	40
3000	60
4000	75
6000	150
8000	180

36. Polypropylene glycol (polyoxy-1, 2-propanediyl) is abbreviated to the acronym "PPG". Polypropylene glycol homopolymers are named as PPG-X, where X is the average number of propylene oxide monomer units, e.g., PPG-10.

    Esters and ethers of polypropylene glycol homopolymers are named as PPG derivatives, e.g., PPG-10 stearate, PPG-10 lauryl ether.

    Other propoxylated substances are named accordingly.

Table 3.3. continued

37. PEG and PPG polymers or their derivatives in which one of the terminal primary alcohol groups (-CH2OH) has been oxidized to a carboxylic acid (-COOH) are named by adding the term "carboxylic acid" or "carboxylate" to the parent name of the original polymer, e.g. PEG-10 carboxylic acid, Coceth-7 carboxylic acid, Ammonium laureth-8 carboxylate.
38. The term "Pareth" applies to ethoxylated parffinic alcohols containing both even- and odd-carbon chain length fractions.
39. The term "Acrylates" is used to describe linear, non-cross linked copolymers that contain combinations of acrylic acid, methacrylic acid and their methyl, ethyl, propyl or butyl esters. Similarly, the term "Crotonate(s)" is used to describe the copolymers that contain combinations of crotonic acid and its methyl, ethyl, propyl or butyl esters.
40. The name "Carbomer" is used to describe high molecular weight cross-linked homopolymers of acrylic acid. The cross-linking agent(s) is (are) identified in the ingredient entry definition. (See also rule 41)
41. The term "cross-polymer" is used to describe polymers other than Carbomer that are cross-linked. (See also rule 40)
42. The term "Poloxamer" denotes a symmetrical block copolymer formed by ethoxylation of polypropylene glycol. Substances with differing degrees of polymerization are further identified by a code number derived from the molecular weight of the polymer.
43. The term "Meroxapol" denotes a symmetrical clock copolymer formed by the propoxylation of polyethlene glycol. Substances with differing degrees of polymerization are further identified by a code number derived from the molecular weight of the polymer.
44. The term "Poloxamine" denotes a symmetrical block copolymer formed by successively propoxylating then ethoxylating ethylene diamine. Substances with differing degrees of polymerization are further identified by a code number derived from the molecular weight of the polymer.
45. Copolymers of ethylene glycol and propylene glycol which do not form symmetrical block copolymers are named as PEG/PPG-X/Y derivatives where X and Y are the average number of ethylene oxide and propylene oxide monomer units respectively.
46. The term "Alkoxyno-n" means an ethoxylated alkyl phenol where n indicates the average number of ethylene oxide units.

When the name is:	the alkyl is:
octoxynol	tetramethylbutyl
nonoxynol	nonyl
dodoxynol	dodecyl
pentadoxynol	pentadecyl

47. Biotechnological materials are substances derived by the action of microorganisms, such as bacteria or yeasts, on a substrate to produce materials by fermentation, metabolism, hydrolysis, lysis or other processes. The process may involve the use of nutrients or other materials such as enzymes. The resulting product is referred to as a "culture" or "ferment". The ferment can be further processed by extraction, filtration, and/or other procedures to yield the final product.

The conventions used to provide INCI names for biotechnological materials are as follows:

(a) When the end product produced from a given "ferment" or "culture" has a common or usual name, such name may be used, e.g., Yogurt, Gellan Gum or Xanthan Gum.

(b) When the end product does not have a common or usual name, the product will be named using the genus of the microorganism, followed by a slash and the name of the substrate (if applicable), followed by the work "ferment". Substrates will be identified by their common, usual, or other technical name, e.g., Lactococcus/Carrot Ferment. On a case-by-case basis, the genus and species name of the microorganism may be used when the used of the genus only may be misleading and the identification of the species is needed for clarity, e.g., Candida bombicola Ferment.

(c) If the selected components of the ferment have been isolated and purified to a significant extent and analytical evidence is provided, the name for one or more of the components may be used, e.g., Glycosphingolipids, Beta-Glucan or Dextran.

48. The term "Ceramide" as part of an INCI name will be assigned to those classes and structures of natural lipids derived from skin as reported by Wertz P.W., Miethke M.C., Long S.A., Strauss J.M. and Downing D.T. in *"The composition of ceramides from human stratum corneum and from comedones"*, The Journal of Investigative Dermatology, 84, 410-412 (1985).

    A synthetic N-acylated sphingoid base that is identical to any one of the many constituents of the natural ceramides, as reported by Wertz, will be assigned an INCI labeling name using the term ceramide followed by a number (e.g., Ceramide 3) or a number and Roman numeral (e.g., Ceramide 6II). The term ceramide as part of the INCI name will only be assigned to a synthetic N-acylated sphingoid base that contains, as the predominant component, the erythro isomer of at least one of the many natural ceramides described by Wertz. A predominant component is one that is present at the highest concentration in relation to other synthetic materials of similar structure and related composition present in a mixture.

    Synthetic N-acylated sphingoid bases that do not have the erythro configuration, or otherwise are not constituents of natural ceramides as described by Wertz, will not be named using the term ceramide. In such cases, a chemical or other appropriate name, to be determined by the International Nomenclature Committee (INC) on a case-by-case basis, will be assigned as the INCI labeling name. The INC may accept a signed statement by a person requesting the assignment of an INCI name that a synthetic N-acylated sphingoid base is the erythro isomer and otherwise conforms in composition to the above criteria.

49. The term "Aminoacrylates" refers to simple aminoacrylates, in which the substituted alkyl groups attached to amino nitrogen range from C1-4, and acrylates conforms to the definition as described in rule 33.

50. Synthetic peptides consisting of 2–10 amino acid residues are named using the appropriate prefix, di-, tri-, tetra-, etc., followed by the term peptide and an arbitrary number, e.g., Dipeptide-2.

    Synthetic peptides consisting of 11–100 amino acids are designated by the term oligopeptide, followed by an arbitrary number.

Table 3.3. continued

Synthetic peptides consisting of more than 100 amino acids are designated by the term polypeptide, followed by an arbitrary number.

The amino acid residues composing the peptide are listed alphabetically in the entry definition in Section 1.

The amino acid residues may include the following:

Alanine	Glutamine	Phenylalanine
Arginine	Glycine	Proline
Asparagine	Histidine	Serine
Aspartic Acid	Isoleucine	Threonine
Cysteine	Leucine	Tryptophan
Cystine	Lysine	Tyrosine
Glutamic Acid	Methionine	Valine

51. Polymer nomenclature—Polymeric materials are named according to the name in common usage if it is well known, or by the structure if well defined. If no common name exists, and the structure is not well defined, the polymers are named according to their source, as described below. Homopolymers (consisting of one constituent monomer) are named by placing the term 'poly' before the constituent monomer, e.g., Polyisobutene.

    Copolymers and Crosspolymers (consisting of two or more constituent monomers) are named by listing the monomers separated by a slash (/) followed by the work "Copolymer" or "Crosspolymer", respectively, e.g., Acrylates/Acrylamide Copolymer, Acrylates/VA Crosspolymer.

    Copolymers consisting of four or more monomers may be given an INCI name according to their class followed by an arbitrary number, e.g., Polyester-1, with the monomers listed in the entry definition of the material. Such nomenclature is granted at the discretion of the INC, with a purpose of shortening lengthy INCI names.

    Thus far, the only classes of polymers to be created for this type of nomenclature are Polyesters, Polyacrylates and Polyurethanes. More classes may be added in the future, if the need arises.

Sources For Ingredient Nomenclature

Originally Published in Cosm Toil 110 (5) 29-31 (1995)

The CTFA did not arbitrarily create ingredient names for the INCI nomenclature system. It relied upon information supplied by chemical vendors and other existing sources of chemical identification.

To prepare a cosmetic product's ingredient listing, chemists should look to the following sources to find the appropriate nomenclature:

1. US Code of Federal Regulations (21 CFR 701.30) for list of ingredients named by the FDA
2. International Cosmetic Ingredient Dictionary for INCI and Colour Index names
3. US Pharmacopeia (USP)

4. National Formulary (NF)
5. Food Chemicals Codex (FCC)
6. USAN and the USP Dictionary of Drug Names

Finally, if suitable nomenclature is not found in any of these sources, a technical name or description, or a name that is generally recognizable by consumers may be employed.

Nomenclature Systems

Silicones: Not all cosmetic ingredients are based on fatty acid chemistry. Silicon-based ingredients, common in personal-care products for lubrication, moisturization and conditioning, have their own special nomenclature. As an example, the structure of dimethicone (**Figure 3.1**) would be hard to deduce from its INCI name alone. Dimethicone (or dimethyl-polysiloxane) is a mixture of fully methylated linear siloxane polymers end-blocked by trimethylsiloxy units. The industry uses literally hundreds of other silicon derivatives based on this chemistry. These include dimethicone copolyol (dimethicone with polyoxyethylene groups added to improve water solubility) and cyclomethicone (cyclic dimethyl polysiloxane), known for its lubricity and volatility.

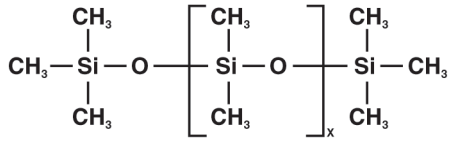

Figure 3.1. CTFA Form TN

Ethanol: Alcohols are another cosmetic raw material with specialized nomenclature requirements. Chemists unfamiliar with the INCI system might presume that ethanol—two simple carbon units and a hydroxyl group—would be one of the easiest ingredients to name. Wrong! Because the ethanol employed in most cosmetic products contains some form of denaturant to deter human consumption, naming them requires specialization.

In fact, the International Cosmetic Ingredient Dictionary does not show "ethanol" per se. Instead, it displays a list of "specially denatured alcohols" (SDA), each with an abbreviation to specify the denaturant. Ethanol denatured with t-butyl alcohol and sucrose octaacetate is SDA 40-A, but ethanol with methyl alcohol is SDA 3-A. In all, the fifth edition of the dictionary lists 26 denatured ethyl alcohols. In the European Union, "alcohol denat" refers to denatured ethanol using an additive approved by the appropriate member states.

Colorants: INCI colorant nomenclature depends upon the regulatory status of the subject material. Most synthetic pigments used in cosmetics are regulated in the United States by the FDA. These, known as certified colors, have difficult and unwieldy chemical names. Fortunately, INCI classification abbreviates colorants according to their approved usage in either the FD&C (Food, Drug and Cosmetic),

D&C (Drug and Cosmetic) or Ext. D&C (External Drug and Cosmetic) certification. Examples include FD&C blue no. 1 (for which common alternate names are brilliant blue or food blue 2), D&C green no. 5 (alizarine cyanine green) and Ext. D&C yellow no. 7 (naphthol yellow S).

In the EU, colorants are identified in the Colour Index (CI) by an internationally recognized 5-digit code. The CI nomenclature is now being listed by CTFA as an alternate INCI name. Thus, FD&C blue no. 1 is also CI 42090.

Some classes of colorant, not requiring special certification, are identified differently. Two common examples are the iron oxides (such as cosmetic black and cosmetic brown) and the ultramarine colors (ultramarine blue, pink and green). Color-imparting cosmetics frequently use these insoluble pigments.

Basic dyes are primarily used as permanent or semipermanent hair colorants. Examples include basic blue 9, also known as 3,7-bis (dimethylamino)phenothiazin-5-ium chloride and basic brown 16, or [8-[(p-aminophenyl) azo]-7-hydroxy-2-napthyl]trimethylammonium chloride.

Other ingredients: Though there appears to be an endless number of chemical designations and abbreviations, the INCI system also uses many easily recognizable names for natural and natural-derived ingredients. These include beeswax, lanolin, menthol and a host of other animal-, vegetable- and mineral-derived components.

The manner in which INCI names are assigned to so-called natural materials depends upon their composition. Materials of biological origin, such as "hyaluronic acid," are named by specific terms once they have been isolated and purified.

When the exact components in a mixture can not be reasonably classified, as with certain plant extracts, the source may be used to name the material. "Aloe vera," for example, identifies the material extracted from the plant of the same name. Other noteworthy examples include keratin protein, vegetable gums, and various mineral waxes. Such familiar terms ease the obvious difficulty of assigning IUPAC names to materials that are mixtures of many compounds.

Fragrances are designated by the comparatively mundane and non-descriptive qualifier "fragrance," though they may be elaborate concoctions of exotic elements like Siberian pine needles, whale musk and rose petal extract. No further chemical identification is required. However, in circumstances where specific aroma chemicals are cited on ingredient statements, the INCI nomenclature should be used. For example, "chamomile" is the name given to the fragrance oil extracted from the plant of the same name.

In a system this complex, there are bound to be cases that just don't make sense scientifically. What is the structural reason for assigning the names carbomer or poloxamer to these common cosmetic thickeners? To confound matters, if an ingredient is considered to be proprietary or a trade secret, its vendor can petition the FDA to allow that material to be listed as simply "other ingredients" on labeling for the US market. In addition, if an incidental material is present that has no function or effect on the formula, or if it is present at an insignificant level, it need not be declared on the ingredient listing.

Water, perhaps the most common of all cosmetic ingredients, can only be legally identified as "water." Despite the efforts of many companies, misnomers such as "deionized," "distilled," "glacier" and "fresh mountain stream" water are not accepted terminology.

INCI Name Assignment Procedures

INCI names are assigned by The Personal Care Products Council, formerly CTFA International Nomenclature Committee (INC), comprised of industry experts that meet approximately quarterly. In order to have an INCI name assigned to an ingredient, the supplier must submit data about the ingredient on CTFA Form TN. This form, available atwww.ctfa-buyersguide.org, asks for such information as chemical structure, Chemical Abstracts Service (CAS) number, and manufacturing method. There is currently a fee of $200.00 to register a new product.

Because INCI names are assigned to ingredients based upon the written information provided by the ingredient's supplier, it is the supplier's responsibility to ensure that the information submitted is complete and accurate.

Once Form TN is received by CTFA, a preliminary literature search is performed on the ingredient, and the submitting firm is contacted for any deficiencies in the application.

The Form TN is then reviewed at the next INC meeting. The INC either assigns an INCI name, or finds that additional information is still required about the ingredient.

After the meeting, the submitter is informed officially by CTFA of the INC's decision.

Companies wishing to change an INCI name must send a written request to the INC. Such requests must include supporting information, including the rationale for the change, alternate nomenclature, information on the structure or composition of the material, and analytical data, if applicable.

Labeling with INCI Names

Some specific conventions for INCI names exist that must be observed when ingredient labeling. Two of the most important are discussed below.

Solvents and diluents: Solvents and diluents in raw materials such as surfactants and polymers are not identified as part of the INCI name. However, diluents and/or solvents must be listed on the package label in their proper order of predominance with respect to all other ingredients in the formulation. Information on the concentration of solvents and/or diluents contained in such raw materials must be obtained from the supplier.

Incidental ingredients: Incidental ingredients contained in cosmetic raw materials are not included in the INCI name. Incidental ingredients include antioxidants, preservatives or processing aids that are present for a specific function in a raw material, but are not intended to have a technical or functional effect in the finished cosmetic product, and are present at insignificant levels in the finished cosmetic product.

Additional Information

The CTFA has published additional information on the labeling requirements for products marketed in the United States[1] and on the regulatory status of colorants in the United States and many other countries.[2]

INCI Information Sources

In the United States:
The Personal Care Products Council
1101 17th Street, N.W., Suite 300
Washington, DC 20036 USA
Phone: 202-331-1770
Fax: 202-331-1969

In the EU:
COLIPA, The European Cosmetic, Toiletry and Perfumery Association
Rue du Congrès 5-7
B-1000 Bruxelles
Belgium
Phone: 011-32-2-227-6610
Fax: 011-32-2-227-6627

Conclusion

The ability to provide timely, accurate, meaningful and consumer friendly names for cosmetic products remains a challenge. Consumer friendly is a key concept. One recent Internet article states consumers should avoid sodium ether sulfate because it contains ether, which will put the user asleep. As long as this type of "knowledge" is disseminated, we in our industry will all have the challenge of explaining consumer confusion.

Published in February 2001 *Cosmetics and Toiletries* magazine.

References

1. *CTFA International Color Handbook*, Second Edition, The Cosmetic, Toiletry, and Fragrance Association, Washington, DC: (1992)
2. *CTFA International Regulatory Resource Manual*, Fourth Edition, The Cosmetic, Toiletry, and Fragrance Association, Washington, DC: (1995)

Chapter 4

INCI Names: International Harmonization

This chapter discusses differences between INCI names in the US Japan and the EU as well as some regulation differences.

key words: nomenclature, INCI, International Nomenclature Cosmetic Ingredient, regulation, EU, labeling

In Chapter 3 "Cosmetic Ingredient Nomenclature", the FDA, the Personal Care Product Council and the process of naming cosmetic ingredients was discussed. This chapter focuses on the harmonization and exceptions that exist between the United States, the European Union and Japan.

INCI (International Nomenclature Cosmetic Ingredient) names are the labeling names that must be used on finished cosmetic product labels in the United States (US), the countries of the European Union (EU) and many other countries. The names are listed in the International Cosmetic Ingredient Dictionary and Handbook[1] (the *Dictionary*), published biannually in the US. The Dictionary also contains information on the chemistry of the INCI named ingredient, including chemical structure, cosmetic function, chemical synonyms and regulatory information.

Differences between the US and the EU

For the most part, INCI names are the same in the US and the EU markets. However, a few notable exceptions do exist. National laws and regulations dictate these differences.

The types of ingredients most frequently affected are:

- Colorants;
- Botanicals;
- Denatured alcohol;
- EU trivial names;
- Fragrance and flavor.

The differences for each of these ingredient types are discussed below.

Colorants that are not hair dyes: Colorants (excluding hair dyes) approved for use in the US are listed in Title 21 of the US Code of Federal Regulations, Parts 73, 74 and 82. The INCI names for these colorants are found in the Dictionary in Section 3 under one of three headings: Color Additives—Batch Certified by the US Food and Drug Administration; Color Additives—Exempt from Batch Certification by the US Food and Drug Administration; Color Additives Lakes—Batch Certified

by the US Food and Drug Administration. Batch certification is the US Food and Drug Administration's (FDA) method of verifying that each individual batch of organic color additives meets the standards and specifications found in Title 21 of the US Code of Federal Regulations, Part 74. Colorants can be classified as either organic or inorganic, depending on their chemistry. A "lake" is the insoluble form of an organic colorant.

Table 4.1. Examples of abbreviated INCI names for batch certified colorants

INCI Name	Unabbreviated FDA Batch certification name
Red 6	D&C Red No. 6
Ext. Violet 2	Ext. D&C Violet No. 2
Red 40 Lake	FD&C Red No. 40 Aluminum Lake

The INCI names for US color additives that are subject to batch certification are abbreviated labeling names. As such, the cosmetic product manufacturer may choose to omit from the product label such terms as "FD&C" (Food, Drug and Cosmetic), "D&C" (Drug and Cosmetic), "No."(Number) and the laking agent. **Table 4.1** shows examples of abbreviated INCI names for batch certified colorants.

Colorants approved for use in the EU may be found in Annex IV of the European Commission Cosmetic Directive (Dir. 76/768/EEC—June 1991, with additional Commission Directives).

With a few exceptions, colorants are listed in Annex IV by the Colour Index (CI) numbers. The INCI labeling name for lakes and salts of EU colorants, not otherwise prohibited in Annex II or regulated by Annex V (Dir. 76/768/EEC—June 1991), is the same CI number as the colorant found in Annex IV, without reference to the laking agent or salt. These INCI names may be found in the Dictionary in Section 3 under the heading Color Additives—Approved in the EU.

Industry has proposed that a dual declaration of colorants with both the US name and the EU name be allowed on labels of cosmetic products intended for sale in both the US and the EU markets. Examples of harmonized names are as follows:

Green 3 (CI 42053)
Ultramarines (CI 77007)

Although the FDA has indicated a willingness to accept this approach as an interim step while it considers the question of harmonized ingredient labeling, CTFA has been informed that certain EU member states have refused to accept this approach.

Persons using harmonized INCI labeling names on products intended for both the US and the EU markets must ensure that the colorants conform with regulatory requirements for the US and the EU.

Colorants that are hair dyes: US laws and regulations do not require batch certification of organic colorants used in hair dyes. There are certain labeling

requirements, however, for these so-called "coal-tar" dyes, a term relating to their original source in the 19th century.

The INCI names for hair colorants in the US and EU are equivalent, and with few exceptions are based on the chemical structure of the ingredient. For a simple structure, the chemical name of the colorant is used. When the chemical structure is very complex, a combination of letters and numbers may be assigned with the prefix "HC". In addition, the names of colorants as listed in the Colour Index may be used. Examples of INCI names of hair colorants include:

HC Blue No. 4
Acid Red 14
2-Amino-5-Nitrophenol

These INCI names may be found in the Dictionary in Section 3 under the heading Color Additives—Hair.

Botanicals: Cosmetic ingredients physically derived from plants are known as botanicals. Generally, these ingredients have not undergone significant chemical modification and include preparations such as extracts, juices, distillates, powders and oils.

In the US, INCI names for botanicals include the Latin binomial (genus and species names), the common name of the plant (if applicable), the plant part, and the type of preparation; for example, Avena Sativa (Oat) Kernel Extract.

In the EU, the INCI names for botanicals currently list only the Latin binomial; for example, Avena Sativa.

The harmonized INCI name for both markets in this case would simply be the US INCI name, Avena Sativa (Oat) Kernel Extract.

It should be noted that at the time this chapter was written, a proposed update to the EU inventory of cosmetic ingredients lists the plant parts and preparations for the labeling of botanicals. Readers are advised to check the EU regulations for the status of this proposal.

Denatured alcohol: Alcohol Denat. is the established INCI labeling name for ethyl alcohol that is denatured (rendered non-potable) in accordance with national regulations in the EU member states and in the US.

In the US, the names and formula specifications for specially denatured (SD) alcohols are listed in the US Department of the Treasury Regulations under Title 27, US Code of Federal Regulations, Parts 20 and 21.

For the US market, labelers may use either the SD Alcohol name or Alcohol Denat. on product labels. For products intended to be marketed in the US and the EU, the name Alcohol Denat. should be used.

EU trivial names: In the EU, "trivial" names are listed in the EU Inventory of Cosmetic Ingredients, and are included in the Dictionary as well. These names represent common names that should be easily recognized by consumers in the EU, where 11 different languages are spoken. The trivial names are based primarily on designations taken from the European Pharmacopeia[2]. Examples of such labeling names harmonized for the US and the EU markets are as follows:

Water (aqua)
Beeswax (Cera alba)
Sea Salt (Maris Sal)

Fragrance and Flavor: The terms Fragrance and Parfum are used as INCI labeling names in the US and the EU, respectively. These names are used to identify that a product contains a material or combination of materials to produce or to mask a particular odor.

The terms Flavor and Aroma are used as INCI labeling names in the US and the EU, respectively. These names are used to identify that a product contains a material or a combination of materials to produce or to mask a particular flavor.

International Harmonization

The information below is taken from the www.ctfa.org site and is designed to provide basic information on the relationship between US regulations and those experienced in other parts of the world. The harmonization of the regulations is both complex and ever changing. This information is offered for basic understanding however the reader is cautioned to review any changes and to get the advice of an expert when attempting to act on this information.

The United States and European Union: Strictly Regulating Cosmetic Safety

The United States (US) and European Union (EU) both work to ensure the safety of cosmetics for consumers through rigorous regulation. In the United States, the cosmetics industry is regulated by the US Food and Drug Administration (FDA), which has been granted broad regulatory authority under the federal Food, Drug and Cosmetic Act, enacted in 1938. The 27 European Union Member States have transposed the European Union Cosmetics Directive, enacted in 1976, into national law. Each Member State has health authorities, which then regulate cosmetics within their respective national boundaries according to the law.

In both the US and the EU, cosmetics manufacturers ensure product safety prior to marketing, list all ingredients on the product label and comply with any restrictions that are established for cosmetic ingredients and products. Any potential risk from a product is assessed as part of its safety evaluation.

In the US, the Cosmetic Ingredient Review (CIR) Expert Panel conducts independent safety reviews of ingredients as a part of the cosmetic safety process, with the results published in the International Journal of Toxicology and on the CIR website. The EU Scientific Committee on Consumer Products (SCCP) is responsible for reviewing all special and active cosmetic ingredients and assessing conditions for safe use. The results are subsequently published on the SCCP website.

In the US, cosmetic and personal care products companies work with leading scientific and medical experts every day and invest millions of dollars in sophisticated laboratory equipment and facilities to ensure cosmetic product safety. In addition to this strong commitment to safety, federal law requires that every cosmetic product be substantiated for safety before it goes to market. The FDA statistics confirm that cosmetics are one of the safest product categories used by Americans today.

The US and EU have slightly different ways of regulating the cosmetic and personal care industry, but both systems provide consumers with a high degree of safety. Some argue that cosmetics are more strictly regulated in the EU, citing recent actions taken in the EU to red flag or ban certain chemicals from use in cosmetics. However, an examination of Annex II of the EU Cosmetics Directive, a list of 1,300 banned ingredients, reveals that a large number of those chemicals are not used and never have been used in cosmetics in the US or Europe. For example, the EU list includes substances such as jet aircraft fuel, various petroleum refinery byproducts and carbon monoxide.

Another difference between the EU and US systems of regulating cosmetics is that the EU allows the marketing of cosmetic products with certain medicinal effects, while the United States has required extra regulatory hurdles because they are classified as drugs. Some of the substances include sunscreens, anti-caries toothpaste and lip balms. Even though color additives are not classified as over-the-counter (OTC) drug actives, they are also subject to more regulatory scrutiny in the US than they are in Europe.

Cosmetic Regulation in Japan

The Japanese government regulates the cosmetics industry through its Ministry of Health, Labor and Welfare according to the Pharmaceutical Affairs Law (Law No. 145) established August 10, 1960. Japan has adopted a list of prohibited ingredients, a list of restricted ingredients, a positive list of UV filters and a positive list of preservatives.

Other than these restrictions, the burden of ensuring product safety has been shifted to cosmetic manufacturers. As such, any ingredient that can be shown to be safe may be used in a cosmetic product. Until recently, a manufacturer or importer of cosmetics was required to obtain a pre-market approval and license from the Ministry of Health, Labor and Welfare. Since 2001, however, Japanese cosmetics companies are required only to provide notification of the product's brand prior to manufacturing or importing.

Japan is an excellent example of a nation where costly pre-market registration procedures were replaced with manufacturer responsibility for product safety and with post-market surveillance (similar to the systems in the US and EU) without compromising consumer safety.

Original: Japanese
Provisional Translation

Standards for Cosmetics
(Ministry of Health and Welfare Notification No.331 of 2000)

In accordance with the provisions of Article 42, Paragraph 2 of the Pharmaceutical Affairs Law (Law No.145 of 1960), the Standards for Cosmetics are hereby established as follows and shall be applied from April 1, 2001, and the Quality Standards for Cosmetics (Ministry of Health and Welfare Notification No.321 of August 1967) and the Japanese Standards for Cosmetic Ingredients (Ministry of

Health and Welfare Notification No.322 of August 1967) shall be abolished on March 31, 2001; provided, however, that any medical drug ingredients which are also cosmetic ingredients that have actually been approved pursuant to Article 14, Paragraph 1 of the said law at the time of application of this notification or which are also cosmetic ingredients listed in the Appendix of the Ministry of Health and Welfare Notification No.15 of February 1961 (Re: Designation of Cosmetic Ingredients that must be Approved for Each Item in Accordance with the Provisions of Article 14, Paragraph 1 of the Pharmaceutical Affairs Law) may, regardless of the provisions of section 2 below, be used as cosmetic ingredients only if used in the amount for which the cosmetic ingredient was approved or the amount of the cosmetic ingredient as listed in the said Appendix, as the case may be; and provided further, that any cosmetics manufactured or imported on or before March 31, 2001, shall be treated as though this notification were not established.

Standards for Cosmetics

General provisions

1. Ingredients of cosmetics, including any impurities contained therein, shall not contain anything that may cause infection or that otherwise makes the use of the cosmetics a potential health hazard.
2. Prohibition of inclusion of ingredients other than preservatives, UV absorbers and tar colors

   Cosmetics shall not contain any medical drug ingredients (excluding those used only as additives and those listed in Appendix 4.2-1 through 4.4), or any ingredients that do not meet the Standards for Biological Materials (Ministry of Health, Labour and Welfare Notification No.210 of 2003), Class I Specified Chemical Substances provided in the Law Concerning the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. Article 2, Paragraph 2 (Law No.117 of 1973), or Class II Specified Substances provided in the same law Article 2, paragraph 3 or the materials that are determined by the Minister of Health, Labour and Welfare and have property similar to these substances, or any of the materials listed in Appendix 4.1.
3. Limitation on inclusion of ingredients other than preservatives, UV absorbers and tar colors

   If any of the materials listed in the section of ingredient names of Appendix 4.2 is incorporated in a cosmetic, the amount of such ingredient contained shall be under the values in the column of maximum amount of ingredient per 100 g of the said Appendix.
4. Limitation on inclusion of preservatives, UV absorbers and tar colors

   Any and all preservatives (meaning materials incorporated in cosmetics for the purpose of inhibiting growth of microorganisms in such cosmetics) incorporated in cosmetics shall be among those listed in Appendix 4.3.

   Any and all UV absorbers (meaning materials that specifically absorb ultraviolet rays and that re incorporated in cosmetics for the purpose of protecting skin

or hair from adverse effects of ultraviolet rays) incorporated in cosmetics shall be among those listed in Appendix 4.4.

The provisions of Article 3 of the Ministerial Ordinance for the Designation of Tar Colors That May Be Used in Medical Drugs, Etc. (Ministry of Health and Welfare Ordinance No.30 of 1966) shall be applied mutatis mutandis to tar colors incorporated in cosmetics; provided, however, that Red No.219 and Yellow No.204 may be incorporated only in cosmetics applied to hair and nails.

Appendix 4.1

1. 6-Acetoxy-2,4-dimethyl-m-dioxane
2. Antihistamines except those of aminoether type (such as diphenhydramine)
3. Hormones and those derivatives except estradiol, estrone and ethinylestradiol
4. Vinyl chloride monomer
5. Methylene chloride
6. Bismuth compounds other than bismuth oxychloride
7. Hydrogen peroxide
8. Cadmium compounds
9. Sodium perborate
10. Chloroform
11. Progrenolone acetate
12. Dichlorophene
13. Mercury and its compounds
14. Strontium compounds
15. Sulfamide and its derivatives
16. Selenium compounds
17. Nitrofuran type compounds
18. Hydroquinone monobenzylether
19. Halogenated salicylanilide
20. Vitamin L1 and Vitamin L2
21. Bithionol
22. Pilocalpine
23. Pyrogallol
24. Inorganic fluorine compounds
25. Pregnanediol
26. Local anesthetics such as procaine
27. Hexachlorophen
28. Boric acid
29. Formalin
30. Methyl alcohol

Appendix 4.2

1. The ingredients restricted in all types of cosmetics

Ingredient name	Maximum amount of ingredient per 100 g
Aluminum chlorhydroxy allantoinate	1.0 g
Cantharides tincture, ginger tincture or capsicum tincture	1.0 g as total
Phenyl salicylate	1.0 g
Polyoxyethylene laurylether (8-10E.O.)	2.0 g

2. The ingredients restricted according to types or intended purposes of cosmetics

Ingredient name	Maximum amount of ingredient per 100 g
Aerosol agents	Prohibited
Zirconium	
Cosmetics to be washed away immediately after use such as soap or shampoo	0.50 g
Thiram	
Cosmetics other than those washed away immediately after use such as soap or shampoo	
Undecylenic acid monoethanolamide	Prohibited
Thiram	0.30g
Zinc p-phenolsulfonate	2.0 g
2-(2-Hydroxy-5-methylphenyl) benzotriazole	7.0 g
Sodium lauroyl sarcosinate	Prohibited
Cosmetics used in cephalic, mucosa part or the oral cavity, and cosmetics used in other parts, containing lower aliphatic monoalcohols (exclude those containing the said alcohols added to dissolve ingredients in the said cosmetics)	20000 IU as total
Estradiol, estrone and ethinylestradiol	
Cosmetics other than those used in cephalic, mucosa part or the oral cavity, containing no lower aliphatic monoalcohols (include those containing the said alcohols added to dissolve ingredients in the said cosmetics)	50000 IU as total
Estradiol, estrone and ethinylestradiol	
Cosmetics used in only cephalic part	0.010 g
Aminoether type antihistamines	
Cosmetics other than those used only in cephalic part	Prohibited
Aminoether type antihistamines	
Toothpaste	0.50 g
Sodium lauroyl sarcosinate	

Compounds to be used with the purpose of emulsifying beewax or white beewax Sodium pyroborate	0.76 g (limited not to greater than 1/2 amount of beewax and white beewax)
Compounds to be used for purposes other than emulsifying beewax or white beewax Sodium pyroborate	Prohibited

3. The ingredients restricted according to types of cosmetics (*)

	Maximum amount (g) of ingredient per 100 g		
Ingredient name	**Cosmetics not used for mucosa and to be washed away**	**Cosmetics not used for mucosa and not to be washed away**	**Cosmetics that may be used for mucosa**
Thioctic acid	0.01	0.01	
Ubidecarenone	0.03	0.03	

(*)Blank indicates that it is prohibited to be used.

Appendix 4.3

1. The ingredients restricted in all types of cosmetics

Ingredient name	**Maximum amount (g) of ingredient per 100 g**
Benzoic acid	0.2
Benzoate	1.0 as total
Alkyldiaminoethylglycine hydrochloride	0.20
Photosensitizing dyes	0.0020 as total
Chlorcresol	0.50
Chlorobutanol	0.10
Salicylic acid	0.20
Salicylate	1.0 as total
Sorbic acid and sorbate	0.50 as total
Dehydroacetic acid and dehydroacetate	0.50 as total
Trichlorohydroxydiphenylether (Triclosan)	0.10
p-Oxybenzoic acid esters and their sodium salts	1.0 as total
Phenoxyethanol	1.0
Phenol	0.10
Sodium lauryldiaminoethylglycine	0.030
Resorcin	0.10

Appendix 4.3 continued

2. The ingredients restricted according to types of cosmetics (*1)

Ingredient name	Maximum amount (g) of ingredient per 100g Cosmetics not used for mucosa and to be washed away	Cosmetics not used for mucosa and not to be washed away	Cosmetics that may be used for mucosa
Zinc, ammonia and silver substituted zeolite(*4)	1.0	1.0	
Pantothenyl ethylether benzoate	**	0.30	0.30
Isopropylmethylphenol	**	0.10	0.10
Cetylpyridinium chloride	5.0	1.0	0.010
Benzalkonium chloride	**	0.050	0.050
Benzethonium chloride	0.50	0.20	
Chlorhexidine hydrochloride	0.10	0.10	0.0010
o-Phenyl phenol	**	0.30	0.30
Sodium o-phenylphenate	0.15	0.15	
Silver-Copper Zeolite(*5)	0.5	0.5	
Chlorhexidine gluconate	**	0.050	0.050
Cresol	0.010	0.010	
Chloramine T	0.30	0.10	
Chlorxylenol	0.30	0.20	0.20
Chlorphenesin	0.30	0.30	
Chlorhexidine	0.10	0.050	0.050
1,3-Dimethylol-5, 5-dimethylhydantoin	0.30		
Alkylisoquinolinium bromide	**	0.050	0.050
Thianthol	0.80	0.80	
Thymol	0.050	0.050	**(*2)
Trichlorocarbanilide	**	0.30	0.30
p-Chlorphenol	0.25	0.25	
Halocarban	**	0.30	0.30
Hinokitiol	**	0.10	0.050
Zinc pyrithione	0.10	0.010	0.010
Iodopropynyl butylcarbamate(*6)	0.02	0.02	0.02
Polyaminopropyl biguanide	0.1	0.1	0.1
Methyl isothiazolinone	0.01	0.01	

Methylchloro isothiazolinone and methyl isothiazolinone solution(*3)	0.10	
N,N"-Methylenebis[N'-(3-hydroxymethyl-2,5-dioxo-4-imidazolidinyl)urea]	0.30	
p-Dimethylaminostyryl heptyl methyl thiazolium iodide	0.0015	0.0015

(*1) Blank indicates that it is prohibited to be used, and ** indicates that there is no upper limit for the amount of ingredient.

(*2) It can be contained in cosmetics used for mucosa and only for oral cavity.

(*3) It indicates the aqueous solution containing 1.0–1.3% of 5-chloro-2-methyl-4- isothiazolin-3-one and 0.30–0.42% of 2-methyl-4-isothiazolin-3-one.

(*4) It indicates the compound containing 0.2–4.0% as silver and 5.0–15.0% as zinc when it is exposed to strong heat.

(*5) It indicates the compound containing 2.7–3.7% as silver and 4.9–6.3% as copper when it is exposed to strong heat.

(*6) It is prohibited to be contained in aerosol agents.

Appendix 4.4

1. The ingredients restricted in all types of cosmetics

Ingredient name	Maximum amount (g) of ingredient per 100g
Homomenthyl salicylate	10
2-Cyano-3,3-diphenyl prop-2-enoic acid 2-ethylhexyl ester (octocrylene)	10
Glyceryl mono-2-ethylhexanoate di-p-methoxycinnamate	10
p-Aminobenzoic acid and its esters	4.0 as total
4-tert-Butyl-4'-methoxy dibenzoylmethane	10

2. The ingredients restricted according to types of cosmetics (*1)

	Maximum amount (g) of ingredient per 100g		
Ingredient name	Cosmetics not used for mucosa and to be washed away	Cosmetics not used for mucosa and not to be washed away	Cosmetics that may be used for mucosa
4- (2-β-glucopyranosiloxy) propoxy-2-hydroxybenzophenone	5.0	5.0	
Octyl salicylate	10	10	5.0
Methyl-2, 5-diisopropylcinnamate	10	10	
2-[4-(diethylamino)-2-hydroxybenzyl] benzoic acid hexylester	10.0	10.0	

Appendix 4.4 continued

Ingredient name	Maximum amount (g) of ingredient per 100g: Cosmetics not used for mucosa and to be washed away	Cosmetics not used for mucosa and not to be washed away	Cosmetics that may be used for mucosa
Cinoxate	**	5.0	5.0
Dihydroxydimethoxybenzophenone	10	10	
Sodium dihydroxydimethoxybenzophenone disulfonate	10	10	
Dihydroxybenzophenone	10	10	
Dimethicodiethyl-benzal malonate	10.0	10.0	10.0
1- (3, 4-dimethoxyphenyl)-4, 4-dimethyl-1, 3-pentanedione	7.0	7.0	
Dimethoxybenzylidenedioxo-imidazolidine 2-ethylhexyl propionate	3.0	3.0	
Tetrahydroxybenzophenone	10	10	0.050
Terephthalylidene dicamphor sulfonic acid	10	10	
2,4,6-Tris [4-(2-ethylhexyloxycarbonyl) anilino] -1,3,5-triazine	5.0	5.0	
Methylbis(trimethylsiloxy)silyl isopentyl trimethoxycinnamonate	7.5	7.5	2.5
Drometrizole trisiloxane	15.0	15.0	
Amyl p-dimethylaminobenzoate	10	10	
2-Ethylhexyl p-dimethylaminobenzoate	10	10	7.0
Isopropyl p-methoxycinnamate and diisopropyl cinnamate ester mixture(*2)	10	10	
2-Ethylhexyl p-methoxycinnamate	20	20	8.0
2,4-Bis-[{4-(2-ethylhexyloxy)-2-hydroxy}-phenyl]-6-(4-methoxyphenyl)-1,3,5-triazine	3.0	3.0	
2-Hydroxy-4-methoxybenzophenone	**	5.0	5.0
Hydroxymethoxybenzophenone sulfonate and its trihydrate	10(*3)	10(*3)	0.10(*3)

Sodium hydroxymethoxybenzophenone sulfonate	10	10	1.0
Phenylbenzimidazole sulfonic acid	3.0	3.0	
Ferulic acid	10	10	
2,2'-methylenebis(6-(2H-benzotriazole-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol	10.0	10.0	

(*1) Blank indicates that it is prohibited to be used, and ** indicates that there is no upper limit for the amount of ingredient.

(*2) It indicates the compound containing 72.0–79.0% of isopropyl p-methoxycinnamate, 15.0–21.0% of ethyl 2,4-diisopropyl cinnamate and 3.0 - 9.0% of methyl 2,4-diisopropyl cinnamate.

(*3) It is calculated as the total amount of hydroxymethoxybenzophenone sulfonate.

Published February 2001 *Cosmetics and Toiletries* magazine.

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