SECTION 1: BASIC DEFINITIONS

LEARNING OBJECTIVES

Upon completion of this section, the reader will be able to

1. define the following terms:

<table>
<thead>
<tr>
<th>Claim</th>
<th>Personal care product</th>
<th>Cosmetic science</th>
<th>Drugs</th>
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</thead>
<tbody>
<tr>
<td>Cosmeceutical</td>
<td>FD&amp;C Act</td>
<td>Dietary supplement</td>
<td>Soap</td>
</tr>
<tr>
<td>Cruelty-free</td>
<td>USDA</td>
<td>Cosmetics</td>
<td>Organic</td>
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<tr>
<td>Intended use</td>
<td>Hypoallergenic</td>
<td>FDA</td>
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2. discuss whether cosmetic science is really a science or not;
3. discuss what knowledge and background education are necessary if one wants to work in the cosmetic industry;
4. differentiate between a cosmetic and a drug;
5. explain what the main factor is that legally differentiates cosmetics and drugs in the United States;

6. explain how certain products can be both drugs and cosmetics;
7. explain how a cosmetic product’s intended use is established in the United States;
8. explain why cosmeceuticals represent a gray zone between cosmetics and over-the-counter (OTC) drug–cosmetic products in the United States;
9. discuss if dietary supplements are cosmetics or not in the United States;
10. explain what the following terms mean and how their use is regulated in the United States: organic, hypoallergenic, cruelty-free, preservative-free, dermatologist recommended, clinically proven, patented formula, and pH balanced;
11. explain how soaps are regulated in the United States;

**KEY CONCEPTS**

1. Cosmetic science is a real science, and it is a multidisciplinary field since it includes basic knowledge and a wide range of information from a number of different scientific fields.
2. Cosmetics are articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting structure or function.
3. Drugs are articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and articles (other than food) intended to affect the structure or any function of the body of man or other animals.
4. The legal difference between a cosmetic and a drug in the US is determined by a product’s intended use, i.e., what the product is used for.
5. In the US, certain products can be cosmetics and drugs at the same time since they meet the definitions of both cosmetics and drugs.
6. A cosmetic product’s intended use can be established in a number of ways, including claims, consumer perception of the product, and the history of an ingredient.
7. Many claims commonly used today for cosmetic products are not recognized or used by the Food and Drug Administration (FDA) in any sense and have only limited scientific evidence behind them. However, the use of these words is not prohibited, which is why they are used.
8. True soaps are regulated by the Consumer Product Safety Commission and not by the FDA.

**What is Cosmetic Science?**

Generally speaking, science is the organized body of knowledge that is derived from a systematic observation of natural events and conditions and that can be verified or tested by further investigations. Examples for science include chemistry, biology, and physics. Is cosmetic science considered a real science? When trying to answer
this question, we tend to think of information we saw, heard, or read in the news or on TV. In addition, public opinion and religion may also influence the perception of what constitutes a real science. Today, there are a number of doubtful consumers and even professionals who are wondering what cosmetic science is all about. Depending on the source of the information, cosmetic science has been identified as follows:

- **Commercial science** that tries to find reasons for selling a product.
- **Comparative science** based on the fact that many manufacturers compare their own products to other manufacturers’ products and try to convince consumers why to buy their products instead of other companies’ products.
- **Traditional science**, such as chemistry or physics, where there are hypotheses and scientists try to justify or deny them by performing a number of tests and reactions.
- **Borderline science** as it is a transition among a number of different scientific fields, including pharmacy, chemistry, dermatology, and marketing, among others.
- Some consumers believe that it is really **not a science**.

Let us review what knowledge and background education is needed if someone wants to work in the cosmetic industry as a scientist.

- Basic knowledge of **anatomy and physiology** is needed to understand the structure and function of the skin, hair, lips, teeth, and so on, to where products are usually applied.
- To be able to formulate effective, stable, and safe products that have appealing aesthetics, appropriate performance, and compatibility with the application surfaces, it is necessary to understand the basic physical, chemical, and physicochemical properties of the raw ingredients that are typically used. Therefore, a **chemical** background, including organic, inorganic, colloid, and polymer chemistry, is also required.
- To be able to choose appropriate ingredients, the basic properties and therapeutic effects of the raw materials on the target surfaces have to be known. Therefore, a basic **pharmacological** education is also inevitable.
- Future formulators also need to be aware of and understand the different dosage forms from which they can choose to incorporate the ingredients. Additionally, they have to know the various manufacturing techniques that are used to produce the dosage forms. Therefore, they need to be taught **formulation technology**.
- It goes without saying that basic knowledge and understanding of the current **guidelines, rules, and regulations** relevant for cosmetics and OTC (over-the-counter) drug–cosmetic products are essential. As part of the regulations, one needs to be aware of and understand the rules that regulate **labeling and packaging** of a final cosmetic product.
- Education in **analytical sciences** as well as **microbiology** is also important in order to understand the different types of tests and testing methods that are
performed for cosmetics and OTC drug–cosmetic products to evaluate their performance, efficacy, safety, and stability.

- Additionally, understanding what consumers expect from products and what their needs are is also required in order to be able to target those needs and satisfy consumers (consumer needs).
- Finally, basic understanding of marketing and business is essential to understand how a business, such as the cosmetic industry, works.

Based on all of the above, we can conclude that cosmetic science is a real science, and it is a multidisciplinary field since it includes basic knowledge and a wide range of information from a number of different scientific fields. It is involved with developing, formulating, and producing cosmetics and personal care products. See a summary of this information in Figure 1.1.

![Figure 1.1](image)

**Figure 1.1** Scientific areas contributing to cosmetic science.

**Basic Definitions**

*Is It a Drug or a Cosmetic?* Today, we can find cosmetics and personal care products almost everywhere, including grocery stores, pharmacies, beauty salons, or even gas stations. But, what are cosmetics? Is there a definition for them? When people are asked the question “What do you think cosmetics are?” the answer is often “The hundreds of makeup products that my wife puts on her face,” “The products that an aesthetician uses,” “I guess my shaving cream,” or “My antiwrinkle cream.” These answers do not completely cover the spectrum of cosmetics available, and some of them are even not true. You as a health science professional have to be aware of the basic definitions and able to apply them and act in accordance with them.
United States  In the United States, the Food and Drug Administration (FDA) has authority over cosmetic products, drugs, and foods. Within the FDA, the Office of Cosmetics and Colors, which is within the Center for Food Safety and Applied Nutrition (CFSAN), regulates cosmetics (see more information in Section 2 of Chapter 2). The legal responsibilities and requirements are laid down in the Food, Drug and Cosmetic (FD&C) Act, which was introduced in 1938 as a revision of the Food and Drugs Act of 1906. The FD&C Act defines two main categories of products, namely cosmetics and drugs.

- **Cosmetics** The FD&C Act defines cosmetics by their intended use as follows: “Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting structure or function.” Among the products included in this definition are skin moisturizers, lipsticks, nail polishes, eye and facial makeup products, shampoos, permanent waves, hair coloring products, and deodorants as well as any material intended for use as a component of a cosmetic product.

- **Drugs** Drugs are also regulated under the FD&C Act by a different office, namely the Office of Nonprescription Drugs, within the Center for Drug Evaluation and Research (CDER) (see more information in Section 2 of Chapter 2). According to the FD&C Act, drugs are: “Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals.”

As regulated by the FDA, there are two categories of drugs: OTC drugs and prescription-only drugs. OTC drugs can be purchased without a prescription, as their name states. These products are considered safe and effective for use by the general public without a prescriber’s authorization. Examples include products we can buy for headache, sore throat, and allergy. On the other hand, prescription medications require a prescription written by a licensed doctor before they can be purchased by patients. These drugs are not safe for self-treatment for several reasons; this is why they cannot be used without a doctor’s supervision. Examples include antibiotics, contraceptives, and drugs taken for high blood pressure.

The two definitions (i.e., that of cosmetics and drugs) provided by the FD&C Act legally determine whether a formulation is a drug or a cosmetic. It is important to note that the legal difference between a cosmetic and a drug in the US is determined by a product’s intended use, i.e., what the product is used for, and not the ingredients in the product. Therefore, if the intended use relates to the prevention and treatment of a disease, the substance is a drug; if its intended use is described in advertisements as promoting attractiveness, the product is a cosmetic.

You may wonder why you have to know the definition of both cosmetics and drugs if you want to work for the cosmetic industry. At this point, you have to understand that, in the US, certain products can be cosmetics and drugs at the same time if they meet the definitions of both cosmetics and drugs. These products will be
referred to as OTC drug–cosmetic products in this textbook. As described previously, the main factor that legally differentiates a drug from a cosmetic in the US is the intended use of the product. Double function 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 ingredient is considered a drug because it is intended to be used to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug (see Figure 1.2).

Additional examples for products that have both drug and cosmetic functions include the following:

- **Toothpaste** that contains fluoride to prevent tooth decay. Its cosmetic function is to clean and refresh the teeth and oral cavity. The presence of fluoride (e.g., sodium fluoride), however, makes this product to be considered an OTC drug product, which, in addition to cleaning and freshening, also prevents a disease, i.e., tooth decay.
- **Deodorants** that not only mask bad body odor but also alter the normal process of perspiration, i.e., *antiperspirants*.
- **Mouthwash** that contains ingredients to prevent and/or treat gingivitis (i.e., inflammation of the gums).
- **Facial foundations** that also contain sunscreens to protect the skin from the harmful radiation of the sun.
- **Facial cleansers** that contain antiacne active ingredients to prevent and/or treat acne vulgaris.
- **Hand soaps** that contain antibacterial agents to kill germs.

It has to be emphasized that neither the term “OTC drug-cosmetic product” is recognized by the FDA, nor there is an official definition for this terminology. However, these products are subject to the FDA’s regulations for both drugs and cosmetics (not just for drugs as allergy medications). Therefore, this term will be used in this textbook. The purpose of using this terminology is to make readers understand the uniqueness of this category from a regulatory perspective. Simple OTC products, such as painkiller tablets, have only one intended use and do not have any cosmetic function. However, products called OTC drug–cosmetic combination products have both drug and cosmetic functions, which makes them unique among OTC products.
In the US, most cosmetics that are also drugs are considered OTC drugs. These products are regulated by both CDER and CFSAN. There are only a small number of products that are prescription-only drugs and still offer cosmetic benefits for the users.

**DID YOU KNOW?**

While the FDA only defines cosmetics and drugs, consumers and companies often use the terms “personal care product,” “decorative care product,” “makeup,” “color cosmetic,” and “toiletries.” But what are these terms? The term “toiletries” is often used for products that are used to clean the body, hair, and teeth, for example, a bodywash, shampoo, and toothpaste, respectively. This term is quite often used interchangeably with personal care products. The terms “color cosmetics,” “makeup,” and “decorative care products” are generally used for products primarily applied by women to make themselves more attractive, for example, a lipstick, mascara, and nail polish. However, it should be kept in mind that these terms do not reflect the legal state of the products, i.e., whether they are cosmetics or drugs. Even a lipstick can be a drug if it contains sunscreens.

*Definition of Cosmetics in Other Markets* In addition to the US, the major markets for cosmetics are considered to be in Europe, Canada, and Japan. The definitions and regulations of cosmetics in these markets are slightly or significantly different from those in the US and also from one another. It means that the same product types may be categorized in a different way in different markets. It is especially important for companies that export their products from one country to another, since in this case, they have to meet the other countries’ definitions and regulations. To provide readers with a general picture, the basic definitions in these markets are reviewed here.

**European Union** In the European Union (EU), cosmetics are regulated under the Cosmetic Products Regulation (EU Regulation 1223/2009), which replaced the Cosmetics Directive (76/768/EEC of 1976). The provisions of the EU Cosmetic Products Regulation aim at ensuring that consumers’ health is protected and that they are well informed by monitoring the composition and labeling of products. According to the Regulation, a cosmetic is⁹: “Any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips, and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors.”
The requirements and procedures for the marketing authorization of medicinal products for human use, as well as the rules for the constant supervision of products after they have been authorized, are primarily laid down in different regulations, namely Directive 2001/83/EC (which has been amended in 2004 by Directive 2004/27/EC) and Regulation (EC) No. 726/2004. A medicinal product (i.e., drug) is defined as follows: 

(a) Any substance or combination of substances presented for treating or preventing disease in human beings or animals. (b) Any substance or combination of substances which may be used in or administered to human beings or animals with a view to making a medicinal diagnosis or to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action.”

The definition of a medicinal product covers substances that have an effect on the human body. However, as it is agreed in the EU, this definition is only relevant to ingredients that significantly affect the metabolism of the human body. Products such as toothpastes that simply help protect against certain diseases, for example, dental caries, do not qualify them as a medicinal product in the EU member states. 

Now you understand that a cosmetic in the EU can have a mild activity and possess pharmaceutical activity. It results in the fact that sunscreens and antidandruff shampoos, for instance, are considered cosmetics in the EU; however, they are considered drugs in the US. An important difference is that in the EU, a product can be either a cosmetic or a drug but not the combination of both.

**Canada** In Canada, cosmetics and drugs are regulated by Health Canada under the Food and Drugs Act and its Cosmetic Regulations. Let us review how they define these product categories. Legislation in Canada identifies two main categories of products: cosmetics and drugs, including nonprescription (OTC) drugs.

According to Health Canada, a cosmetic product is: “Any substance used to clean, improve or change the complexion, skin, hair, nails or teeth. Cosmetics include beauty preparations (makeup, perfume, skin cream, nail polish) and grooming aids (soap, shampoo, shaving cream, deodorant).”

The Food and Drug Act defines drugs as follows: “Any substance or mixture of substances manufactured, sold or represented for use in (1) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof in man or animal, (2) restoring, correcting or modifying organic functions in man or animal, or (3) disinfection in premises in which food is manufactured, prepared or kept.”

According to Health Canada, a personal care product can be defined as a substance or mixture of substances that is generally recognized by the public for use in daily cleansing or grooming. Depending on the ingredients and the claims of a product (i.e., statements referring to the expected effect of products found on product labels, on the Internet, in advertisements, and in any promotional materials), a personal care product can be regulated as a cosmetic or a drug. As you can see, Canada also differentiates between drugs and cosmetics; however, unlike in the US, a product can be included only within a single category.
In Japan, cosmetics and drugs are regulated by the Ministry of Health, Labour and Welfare (MHLW) under the Pharmaceuticals Affairs Law (PAL). The PAL was first adopted in 1943 and was amended several times until 2001. The current PAL was implemented in 2001, and it is often referred to as the “deregulation” since a number of mandatory requirements were ablated by the new regulation. The PAL defines three relevant categories of products: cosmetics, quasi-drugs, and drugs. According to the PAL of Japan, the term “cosmetic” refers to:

“Items (other than quasi-drugs) with mild action on the human body and which are intended to be applied to the human body by means of rubbing, sprinkling and the like for the purpose of cleaning, beautifying, adding to the attractiveness, altering the appearance, or keeping the skin or hair in good condition.”

Under the same act, the term “drug” is defined as follows:

“(1) Items recognized in the Japanese Pharmacopoeia; (2) items (other than quasi-drugs) which are intended for use in the diagnosis, cure or prevention of disease in humans or animals, and which are not equipment or instruments (including dental materials, medical supplies and sanitary materials), and (3) items (other than quasi-drugs and cosmetics), which are intended to affect the structure or functions of the body of humans or animals, and which are not equipment or instruments.”

Unlike the US, Canada, and EU, Japan has an additional category, the so-called quasi-drugs, and includes products that fall in between the two abovementioned categories. According to the PAL, the term “quasi-drug” applies to:

“Items that have mild action on the human body but are not intended for the uses in the diagnosis, cure or prevention of disease or to affect the structure or function of the body. The purposes of use of quasi-drugs are specified in the PAL as: prevention of nausea or other discomfort, foul breath or body odor; prevention of prickly heat, sores and the like; prevention of hair loss, to promote hair growth, or for hair removal; and eradication of or repellence of rats, flies, mosquitoes, fleas, etc. for the health of man or other animals.”

A quasi-drug is defined in Japan as a product that has minimal to moderate pharmacologic activity but is restricted in use to specific indications. Products in this class include bath preparations, skin whitening products, acne products, antifungal shampoos, fluorinated toothpaste, hair dyes, and many others. These products are considered borderline medicinal products, which are categorized differently in various markets.

Summary  Now that we reviewed the four major markets’ definitions of cosmetics and drugs, you understand that these definitions are not the same and do not cover the same types of products. It results in the fact that a simple product, such as a sunscreen, is defined and regulated in a different way in the US, EU, Canada, and Japan. The most important consequence of this is that it makes import quite difficult. After reading Chapter 2, which is about the rules and regulations of cosmetics and drugs in the US, you will understand that the deviations previously make big differences from a regulatory aspect.
How is a Product’s Intended Use Established in the United States?

You saw that the intended use of the product has an essential role in categorizing a product in the US. But how is the intended use of a product determined? A cosmetic product’s intended use can be established in a number of ways, including claims, consumer perception of the product, and the history of an ingredient.

- **Claims** Claims reflect the expected effects of a particular product. It should be noted that certain claims may cause a product to be considered a drug, even if the product is marketed as a cosmetic. Examples for cosmetic claims include “moisturizes skin,” “cleans hair,” and “freshens breath,” while drug claims include “reduces wrinkles,” “helps prevent chapped lips,” and “restructures the deepest epidermal layers.” Cosmetics cannot be marketed with drug claims; therefore, products sold as cosmetics but advertised with drug claims are subject to regulatory action. In the majority of the cases, the FDA issues a warning letter to the companies making drug claims to their cosmetic products and recommends them to change the wording of their claims in order to avoid regulatory difficulties.

- **Consumer Perception** Consumer perception is established through the product’s reputation. This means asking consumers to fill out questionnaires about why they buy a particular product and what they expect the product to do. It provides a basic understanding of the claims by the consumer. In addition, it reflects whether a claim that was intended to be a cosmetic claim is understood as a cosmetic claim and is not misinterpreted.

- **The History of an Ingredient’s Use** The presence of a pharmacologically active ingredient in a therapeutically active concentration can make a product a drug, even in the absence of explicit drug claims. When an ingredient is known to have drug-like effects (such as sodium fluoride can prevent cavities), and it is incorporated into a product, it will automatically make the product to be considered a drug as the intended use will be the prevention and/or treatment of a disease. Although the explicitly stated intended use is the primary factor in determining the cosmetic versus drug product category, the type and amount of the ingredient(s) present in a product must be considered in determining its regulatory status, even if a product does not make explicit drug claims.

**Popular Cosmetic Claims**

Claims are statements found on product labels, in TV and radio ads, and in magazines, indicating the expected positive effects of a product (e.g., softens and smoothens skin, visibly tightens pores), the look the product provides (e.g., vibrant color, flawless finish), or the absence of ingredients that may cause safety concerns (e.g., paraben-free, noncomedogenic). This part reviews some of the most popular cosmetic claims in the US, such as cosmeceutical, organic, hypoallergenic, and cruelty-free. What do these terms mean? Do they have an official definition for them? Are these recognized by the FDA? The truth is that many of these terms were created by marketing
people to make products sound catchy, innovative, trustworthy and appealing and raise consumer’s interest. Many claims commonly used today for cosmetic products are not recognized or used by the FDA in any sense and have only limited scientific evidence behind them. However, the use of these words is not prohibited, which is why they are used. Since these words are used in TV commercials, in advertisements, and on product labels, it is worth discussing them.

Cosmeceuticals When the term “cosmeceutical” was introduced in the 20th century, it was used for prescription-only products that addressed appearance issues, such as acne. Today, this term is mainly used for multifunctional products that can be purchased as cosmetics and that are advertised to offer additional skin benefits over simple cosmetics. The term itself sounds like the combination of the terms “cosmetics” and “pharmaceuticals” (i.e., drugs), which catches the consumers’ interest.

Cosmeceuticals are generally advertised to contain bioactive ingredients that, although are not drugs, have visible and measurable short-term and long-term effects on the skin, such as improvement of fine lines. Examples for bioactive ingredients include vitamins, antioxidants, proteins, anti-inflammatory agents, and many others.

Although it is a frequently used word by skin care professionals and physicians, the term is not recognized by the FDA. The FDA states “a product can be a drug, a cosmetic, or a combination of both; therefore, the term cosmeceutical has no meaning under the law.” As discussed previously, Japan has a specific category of products that are in between cosmetics and drugs (called quasi-drugs). In the US, however, there is currently no such category.

These products represent a gray zone between cosmetics and drugs (see Figure 1.3) as many of them are sold as cosmetics; however, they may have drug-like

Figure 1.3 The two legal categories of personal care products in the US, i.e., drugs and cosmetics, are shown as black and white, while cosmeceuticals represent a gray zone between these two categories.
effects on the applied surfaces. For example, a number of today’s anti-wrinkle formulations are advertised as cosmeceuticals and sold as cosmetics. As we do not have a long history of use for many bioactive ingredients, we lack the established pharmacological profile for them. Cosmeceuticals are currently defined by the claims made about their intended use and ingredients they contain. For example, a product that “eliminates wrinkles” is a drug, while a product that “minimizes the appearance of wrinkles” is a cosmetic, even though they both may contain the same ingredients.

Nutraceuticals There is a distinct category of products, known as dietary supplements or nutraceuticals, that are often thought to be cosmetics by consumers based on the claims heard on TV and seen on the Internet and printed media (i.e., “beauty from the inside out” and “beauty from within”). These products often claim to make the hair, skin, and nails look healthier, shinier, and stronger.

Although they may be believed to be cosmetics, dietary supplements represent a specific category separate from foods, drugs, and cosmetics. The word “nutraceutical” refers to the combination of natural ingredients and pharmaceuticals. Dietary supplements are also regulated by the FDA; however, they are defined in the Dietary Supplement Health and Education Act (DSHEA) of 1994; it is not the FD&C Act that regulates cosmetics. These products contain dietary ingredients such as vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders. According to the FDA, a dietary supplement is: “A product taken by mouth that contains a dietary ingredient intended to supplement the diet.”

Whatever their form may be, DSHEA places dietary supplements in a special category under the general umbrella of foods, not drugs, and requires every supplement to be labeled as a dietary supplement. Keep in mind that dietary supplements are a legal category; however, they are not cosmetics.

Organic Products Today, there is a growing consumer demand for products containing organic ingredients, also known as natural, ingredients. These ingredients are believed to be healthier and safer than their synthetic pairs. However, this is not necessarily true. An ingredient’s source does not determine its safety. There are many toxins produced by animals and plants that are poisonous to the human body (e.g., the venom of vipers and the poison-dart frog or the alkaloids found in poison hemlock). A more common example is the “poison” (known as cyanogenic glycoside) found in apple seeds and apricot seeds. Their amount in a single apple or apricot is usually not enough to be dangerous to humans, but it is possible to ingest enough seeds to provide a fatal dose and eventually die.
Socrates, a Greek philosopher, was killed by the poison of poison hemlock in 399 BC. Its main alkaloid is a neurotoxin; ingestion in any quantity could result in respiratory collapse and death. The alkaloid causes death by blocking the neuromuscular junction. It results in an ascending muscular paralysis with eventual paralysis of the respiratory muscles, which results in death due to lack of oxygen to the heart and brain.

To many consumers, naturally sounding ingredients, such as aloe extract, chamomile extract, and lemon seed extract, mean natural ingredients and equal safety. However, it should be known that these ingredients can be synthetized in laboratories, which results in the exact same chemical structure and physical characteristics. Therefore, the name of an ingredient does not mean it has a natural origin. A general concern with natural ingredients is that they often contain a mixture of various ingredients, depending on the amount of light, humidity, temperature, and nutrients the plants received during cultivation. In the case of synthetic ingredients, their exact composition is always known and is easy to control; however, this is not true for natural products. Therefore, natural ingredients may have a higher chance of interactions with other ingredients in products. Additionally, we do not have an established safety profile for a number of natural ingredients, and we do not know whether they can cause allergic reactions, and if yes, to what extent. Moreover, the actual prevalence of adverse effects when using organic ingredients is often unrecognized or underreported. Therefore, consumers should be careful with natural ingredients as adverse effects, such as skin irritation, sensitizations, phototoxicity, and allergy, have been reported. The term “organic” is not defined in any of the FDA’s laws or regulations. However, the term is regulated by the Agricultural Marketing Service of the US Department of Agriculture (USDA) as it applies to agricultural products through its National Organic Program (NOP) regulation. In addition to agricultural products (organic foods and beverages), the USDA also certifies cosmetics and personal care products if they contain or are made of agricultural ingredients and can meet the USDA/NOP organic production, handling, processing, and labeling standards. The USDA, however, has not created specific organic standards for formulating and labeling personal care products that contain organic ingredients; the standards used are the same for foods, beverages, and personal care products. The USDA has four categories of ingredients/products based on the amount of organic ingredients in a product and other factors. The categories are the following: 100% organic, organic, made with more than 70% organic ingredients, and made with less than 70% organic ingredients.
Products in order to be labeled “100% organic” must contain only organically produced ingredients. These products can display the USDA organic seal.

Products in the “organic” category must contain at least 95% organically produced ingredients. The regulation has requirements for the remaining 5% as well. These products can also display the USDA organic seal.

Products in the “made with more than 70% organic ingredients” contain at least 70% organic ingredients. They can be labeled “made with organic ingredients.” These products can list up to three of the organic ingredients on the principal display panel (see more information on this type of panel in Section 1 of Chapter 2). The products may not display the USDA organic seal.

Products in the last category cannot use the term “organic” anywhere on the principal display panel. However, they may identify specific ingredients that are USDA certified on the information panel (see more information on this type of panel in Section 1 of Chapter 2). These products may not display the USDA organic seal.

In addition to the USDA, cosmetics and personal care products may be certified by other certification programs, including the ANSI 305 established by the National Sanitation Foundation (NSF) International and the OASIS (Organic and Sustainable Industry Standards) program established by the cosmetic industry.

DID YOU KNOW? Cosmetic products labeled with organic claims must comply with both USDA regulations (or other certifier’s regulations) for the organic claim and FDA regulations for labeling and safety requirements for cosmetics.

When purchasing organic cosmetics and personal care products, consumers should be looking for the certifying agency’s name and/or logo as well as the ingredients being identified as organic. As discussed previously, the name of an ingredient does not refer to its source.

DID YOU KNOW? The NOP is the federal regulatory framework governing organic food. It is administered by USDA. The NOP covers in detail all aspects of food production, processing, delivery, and retail sale.
**Hypoallergenic Products** Hypoallergenic cosmetics are products claimed to produce fewer allergic reactions than other non-hypoallergenic cosmetic products. Consumers with hypersensitive skin and even those with normal skin may be led to believe that these products will be gentler to their skin than non-hypoallergenic cosmetics. However, it should be noted that there is no federal standard or definition for the use of the term “hypoallergenic.” The term means whatever the particular company or consumers want it to mean. Manufacturers of hypoallergenic cosmetics are not required to submit data and test results to the FDA to substantiate their hypoallergenicity claims. The term usually refers to products that do not contain ingredients known to cause allergic reactions, such as fragrances. However, as the use of the term is not regulated, it is recommended that consumers with sensitive skin check the list of ingredients on cosmetic labels and see whether there are any ingredients in the product that may cause problems to them.

**Cruelty-Free Products** “Cruelty-free” or “Not tested on animals” claims can often be found on labels or advertisements. Animal testing is a hot topic all over the world. Various animal protection organizations have protested against testing cosmetic products on animals, and in certain markets, testing has already been prohibited. In the EU, testing of finished products and ingredients on animals has already been prohibited (it is referred to as the testing ban). In addition, marketing of finished cosmetics or cosmetic products that have been tested on animals or that contain ingredients that have been tested on animals is being prohibited after March 11, 2013 (it is referred to as the marketing ban).

In the US, the FD&C Act does not specifically require the use of animals in testing cosmetics for safety. However, the agency advises cosmetic manufacturers to employ whatever testing is appropriate and effective for substantiating the safety of their products. Therefore, it remains the responsibility of the manufacturer to substantiate the safety of both ingredients and finished cosmetic products prior to marketing. It means that animal testing may be used to establish product safety. Alternative methods to replace animal experiments, such as *ex vivo* studies (i.e., studies using tissues from an organism in an external artificial environment), have been developed in the past decade. However, they are still not accepted officially by the regulatory agencies in the US due to various reasons. One of the biggest challenges is to try mimicking the complexity of the human tissues as they act together in an artificial environment.

With respect to the “cruelty-free” and “not tested on animal” claims, there is no legal definition for them. Therefore, companies can use these phrases as they like. An important note is that, even if they use these terms for products that were not tested on animals, it does not mean that the raw materials were not tested on animals years ago when they were first introduced. The FDA says that “a cosmetic manufacturer might only use those raw materials and base their cruelty-free claims on the fact that the materials or products are not currently tested on animals.”

**Preservative-Free Products** Preservatives protect cosmetic formulations from microbiological contamination, for example, overgrowth of molds, yeast, and
bacteria in lotions (see more information in Section 2 of this chapter). As the majority of cosmetic formulations contain water, protection against bacteria, molds, and yeast is essential. All products containing water should contain some types of preservative to provide appropriate beyond use date for their products and safety for consumers. Therefore, a “preservative-free” claim is questionable most of the time. We can rarely find products that have an acceptable shelf life without any preservatives. As the major problem is water, which necessitates the use of preservatives, products not containing water (the so-called anhydrous formulations) do not have to contain preservatives and can still have acceptable shelf life. Other product types that can claim to be “preservative-free” include formulations containing a higher percentage of ethanol, which is widely known to have an antimicrobial activity. In addition, certain products have a specific pH value that does not favor the growth of microorganisms. There are also special types of packaging materials, such as airtight packaging, which ensures the absence of organisms.

DID YOU KNOW?

Water-based cosmetic products provide a perfect environment for microbial growth, and the products’ additional components can serve as nutrients for these microorganisms. It should be kept in mind that a contaminated product (which may show no visible signs of contamination) is much more dangerous for users than preservatives.

It should be noted that one of the most widely and most frequently used preservatives are called the parabens. These ingredients are very effective even in very low concentration; however, they can cause allergic reactions in sensitive consumers. Additionally, concerns arose with regard to the safe use of parabens (see more information in Section 2 of Chapter 3). They were linked to breast cancer and endocrine disruption. Although no study has confirmed the potential risks of using parabens on human health, the claims that they can cause breast cancer and endocrine disruption have been widely spread. As many consumers are afraid of using products containing parabens, many formulators have substituted parabens with other types of preservatives to ensure product longevity. They usually also claim their products to be “paraben-free.” If you see this claim on a product, it refers to the fact that the product does not contain parabens. However, it does not mean that it does not contain any sort of preservatives.

Another frequent claim with regard to preservatives is “no added preservatives.” It means that the product formulators did not add any ingredients to the formulation whose primary function would be preservation. However, there are a number of cosmetic ingredients that have a primary effect, such as skin conditioning, and have a limited antimicrobial property as well. In such cases, the ingredient added for its conditioning activity will also prevent microbial contamination in the product
to a certain extent. These types of preservatives are usually called “nonpreservative preservatives” as their primary function is not the prevention of contamination. Their efficacy, however, may be not as good as that of parabens; therefore, formulations often have to use a higher amount of these ingredients.

**“Dermatologist Recommended” Products** The claim “dermatologist recommended” is commonly used on cosmetic products. It may lead consumers to believe that a medical panel of dermatologists has evaluated the product thoroughly and recommends it based on proven results. The truth is that there is no governing body in the US requiring cosmetic companies to show data on whether a dermatologist, a few, or a large number of them tested and recommend a cosmetic product. A “dermatologist recommended” claim is probably based on a product survey, and one or many dermatologists could have endorsed the product. It would also be valuable to know how many of them were neutral, disliked, or hated the product. In addition, it is also worth mentioning that even ingredients considered safe can initiate allergic reactions in sensitive patients. Therefore, unless the products were tested on a wide majority of users over an extended period of time, such a claim has only a little scientific value.

**“Clinically Proven” Claims** The claim “clinically proven” is scientific and powerful in the consumers’ mind. Since claims made about cosmetic products must be truthful and proven (as required by the Federal Trade Commission, see more information on the FTC in Section 3 of Chapter 2), usually there is a science behind such claims, and companies perform tests to back up their claims. It should be noted that clinical testing is not required for cosmetic products that do not have drug claims. The “clinically proven” claim refers to the fact that a product was tested in a clinical environment on humans; however, the details of the clinical testing are usually not provided. Important factors to consider in the case of clinical studies include the number of participants, whether they truly represent a wider group of usual consumers, skin condition of the participants (whether they had any skin sensitivity, allergy, skin disease, etc.), the use and type of a reference product, length of the study, frequency of application, use of other products, the type of data analysis used in the study, and many other factors. Therefore, the claim “clinically proven” without being aware of the study details is still not very informative.

**“Patented Formula” Claims** Another commonly used claim is the “patented formula.” Consumers believe that a product that has been patented must be more serious and scientific; therefore, it works better than other products. The truth is that patenting a product is often related to the technology of how the product is manufactured and not the actual effect of the product. Therefore, it does not necessarily mean that the product is more effective or has a longer performance.

**“pH Balanced” Claims** Companies that make “pH balanced” claims try to imply some level of superiority over products that do not make this claim. They want consumers to believe that the products will be less irritating and will work better. However, any decently formulated product is formulated in a pH range that is compatible with the skin, hair, underarms, or other application surfaces. A consumer will never
notice a difference between a product that is “pH balanced” and one that is just normally formulated.

**DID YOU KNOW?**

In Canada, the regulatory agency for cosmetics, called Health Canada, has an entire list of acceptable and unacceptable claims for cosmetic products, which provides guidance for manufacturers. In the US, currently there is no such list.

**A Special Category: Soap**

Soap is a category that needs special explanation. This is because the regulatory definition of a soap is different from the way in which people commonly use the word. People usually associate the word “soap” with a cleaning aid used for washing our hands and body. In a strictly chemical sense—and this is the definition that the FDA takes into account—soap is a salt produced from fatty acids (e.g., stearic acid) and alkalis (e.g., sodium hydroxide). It is referred to as ordinary or true soap. True soaps are regulated by the Consumer Product Safety Commission, and not by the FDA. The reason for this is that soap was not included in the first regulation of cosmetics, which is the FD&C Act of 1938, and it has not been included since then. Based on the FDA’s definition for cosmetics, a soap would be clearly a cosmetic, as it will clean our hands and body; however, the regulation excludes it from the definition of a cosmetic. In the following box, you can find the official, legal definition of a true soap:

According to the FDA, a true soap is: “(1) The bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the product’s detergent properties are due to the alkali-fatty acid compounds; (2) and the product is labeled, sold, and represented solely as soap.”

Today, there are only a small number of true soaps in the traditional sense on the market. Most hand and body cleansers on the market are actually synthetic surfactant-based products and go under the jurisdiction of the FDA. These surfactant cleansers are popular because they easily make suds in water and do not form deposits. Some of these synthetic surfactant products are actually marketed as soaps; however, they are not true soaps by the legal definition of the word.

With regard to the claims made by soap manufacturers, a soap can be considered a simple noncosmetic product, a cosmetic, or a drug. If no cosmetic claims are made for a soap, other than that it cleanses our hands and body, and no drug claims are made, a soap is considered a noncosmetic, nondrug product, similar to a dishwashing detergent. If a cosmetic claim is made on the label of a true soap, such as moisturizing or deodorizing, it is considered a cosmetic and regulated by the FDA. If a drug claim is made for a soap, such as antibacterial, antiperspirant, or anti-acne, the product is considered an OTC drug–cosmetic product and regulated by the FDA.
GLOSSARY OF TERMS FOR SECTION 1

Claim: A statement referring to the expected effect of a product found on product labels, on the Internet, in advertisements, and in any promotional materials.

Cosmeceutical: This term is used for multifunctional products that can be purchased as cosmetics and that are advertised to offer additional skin benefits over simple cosmetics.

Cosmetic science: An interdisciplinary science involved with developing, formulating, and producing cosmetics and personal care products.

Cosmetics: The FD&C Act defines cosmetics by their intended use as follows “Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting structure or function.”

Cruelty-free: A term used on cosmetic labels to indicate that no animals were involved in product testing. This term does not have an official FDA definition, and its use is not regulated by the FDA.

Dietary supplement: A product that is intended to supplement the body with vitamins, minerals, herbs, and other ingredients, which may not be consumed in a sufficient amount.

Drugs: The FD&C Act defines drugs by their intended use as follows “Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals.”

FDA: Food and Drug Administration; in the United States, cosmetics and drugs are regulated by the FDA, which is an agency of the US Department of Health and Human Services.


Hypoallergenic: A term used on cosmetic labels to indicate that the product is unlikely to cause allergic reactions. This term does not have an official FDA definition, and its use is not regulated by the FDA.

Intended use: The purpose for what a product is used.

Organic: A term often used on cosmetic labels to indicate the presence of naturally derived ingredients. This term does not have an official FDA definition, and its use is not regulated by the FDA.

Personal care product: A term often used for products that are used to clean the body, hair, and teeth, for example, a bodywash, shampoo, and toothpaste, respectively.

Soap: In a strictly chemical sense, soap is a salt produced from fatty acids (e.g., stearic acid) and alkalis (e.g., sodium hydroxide).

Toiletries: A synonym for personal care products.
USDA: The United States Department of Agriculture, which certifies ingredients and products as organic if they meet the USDA standards and requirements.

**REVIEW QUESTIONS FOR SECTION 1**

**Multiple Choice Questions**

1. Which of the following is necessary if you want to work in the cosmetic industry?
   a) Pharmacology  
   b) Chemistry  
   c) Marketing  
   d) All of the above

2. Which of the following regulates cosmetics in the United States?
   a) Consumer Product Safety Admission  
   b) European Commission  
   c) Food and Drug Administration  
   d) Product manufacturers

3. In the United States, cosmetics are regulated under the ___.
   a) DSHEA Act  
   b) FD&C Act  
   c) IUPAC Act  
   d) CDC Act

4. In the United States, OTC drug–cosmetic products are ___.
   a) Regulated as drugs  
   b) Regulated as cosmetics  
   c) Not regulated  
   d) Regulated as dietary supplements

5. Which of the following is true for OTC drug–cosmetic products?
   a) They are subject to the FDA’s regulations for both drugs and cosmetics  
   b) They are cosmetics that also have drug functions  
   c) They are regulated by the FDA  
   d) All of the above

6. Which of the following is an example for an OTC drug–cosmetics product?
   a) A dry hair shampoo  
   b) A deodorant  
   c) An anticavity toothpaste  
   d) A lipstick
7. Cosmeceuticals represent a "gray" zone between drugs and cosmetics in the US because ___.
   a) They are considered dietary supplements but should be considered drugs
   b) They are sold as drugs but are actually cosmetics
   c) They are sold as cosmetics but may have drug-like effects
   d) They are packaged into gray boxes

8. Which of the following is NOT true with respect to dietary supplements in the United States?
   a) They are regulated as cosmetics
   b) They are a legal category of products
   c) They contain a dietary ingredient intended to supplement the diet
   d) All of the above

9. Which of the following can certify a cosmetic product as organic in the United States?
   a) FDA
   b) USDA
   c) Manufacturer
   d) Customer

10. What is the legal difference between a drug and a cosmetic product in the United States?
    a) Color
    b) Intended use
    c) Application surface
    d) All of the above

11. Which of the following is used to determine the intended use of a product in the United States?
    a) Questionnaire
    b) Claims
    c) Ingredients
    d) All of the above

12. What happens if you add an active ingredient to a cosmetic product?
    a) It will be considered a drug
    b) It will be considered a cosmetic
    c) I do not know, but I will not use it
    d) It will be hypoallergenic
13. Which of the following is TRUE for organic cosmetics in the United States?
   a) They are considered drugs
   b) They are a subcategory of cosmetics, which are recognized by the FDA
   c) They are always safer than cosmetics containing synthetic ingredients
   d) They are cosmetics that contain naturally derived ingredients

14. What is the FDA’s statement on hypoallergenic products?
   a) They are less allergenic than non-hypoallergenic products
   b) There is no such category
   c) Every cosmetic product should be hypoallergenic
   d) They should be used by hypersensitive consumers only

15. Which of the following is NOT true for “true soaps” in the United States?
   a) They can only claim to clean the skin
   b) They are salts of fatty acids and alkalis
   c) They are regulated by the FDA
   d) They are regulated by the Consumer Product Safety Commission

16. In the United States, cosmetic companies are _____ test their products on animals.
   a) Not allowed to
   b) Allowed to
   c) Forced by the government to
   d) None of the above

Fact or Fiction?

_____ a) Natural ingredients are always safer than synthetic ingredients.
_____ b) Even if a product is labeled hypoallergenic, it may contain substances that can cause allergic reactions for some people.
_____ c) Animal testing is prohibited in the United States.
_____ d) The commonly used term “cosmeceuticals” is not recognized by the FDA.
_____ e) Dietary supplements are cosmetics.
You can see two products in the below. Which one is a cosmetic and which one is an OTC drug–cosmetic product? Justify your answer.

REFERENCES

4. FD&C Act Section 201(i)
5. FD&C Act Section 201(g)(1)


14. Health Canada, Food and Drugs Act Section 2


17. Dietary Supplement Health and Education Act of 1994


21. CRF Title 7 Part 205


30. CFR Title 21 Part 701.20
LEARNING OBJECTIVES

Upon completion of this section, the reader will be able to

1. Define the following terms:

<table>
<thead>
<tr>
<th>Target group</th>
<th>Dosage form</th>
<th>Application surface</th>
<th>Color additive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active ingredient</td>
<td>Antioxidant</td>
<td>Chelating agent</td>
<td>Anticaries ingredient</td>
</tr>
<tr>
<td>Flavoring agent</td>
<td>Preservative</td>
<td>Moisturizer</td>
<td>Antidandruff ingredient</td>
</tr>
<tr>
<td>Plasticizer</td>
<td>Solvent</td>
<td>Propellant</td>
<td>Anti-acne ingredient</td>
</tr>
<tr>
<td>Surfactant</td>
<td>Astringent</td>
<td>Thickener</td>
<td>Lip protectant</td>
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<tr>
<td>pH buffer</td>
<td>Sunscreen</td>
<td>Antiperspirant</td>
<td>Cosmetic ingredient</td>
</tr>
<tr>
<td>Abrasive</td>
<td>Sweetener</td>
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</tbody>
</table>

2. list various factors based on which cosmetics and OTC drug–cosmetic products can be classified;
3. list some examples for target groups of cosmetic products;
4. list some examples for application surfaces for cosmetics;
5. list some examples for functions of cosmetic products;
6. differentiate between cosmetic ingredients and active ingredients;
7. explain why cosmetics cannot contain active ingredients;
8. discuss how color additives are regulated in the United States, including premarket approval and batch certification;
9. explain the function of the following types of cosmetic ingredients and provide some examples for each group: abrasives, antioxidants, chelating agents, color additives, flavoring agents, fragrances, moisturizers, pH buffers, plasticizers, preservatives, propellants, solvents, surfactants, sweeteners, and thickeners;
10. explain where a formulator can find a list of active ingredients approved for OTC drugs;
11. explain the function of the following types of active ingredients and provide some examples for each group: antiacne ingredients, anticaries ingredients, antidandruff ingredients, antiperspirants, skin protectants, and sunscreens.
KEY CONCEPTS

1. Cosmetics and OTC drug–cosmetic products can be classified based on the target groups, dosage forms, legal status, application surfaces, function, and numerous other ways.

2. Since cosmetics do not treat any conditions or affect the structure of the skin, they do not contain active ingredients. Cosmetic products contain cosmetic ingredients only.

3. Since OTC drug–cosmetic products are used for the prevention, diagnosis, cure, or treatment of a disease, they contain active ingredients, in addition to the cosmetic ingredients. In these products, cosmetic ingredients are referred to as inactive ingredients.

4. Cosmetic ingredients are used in products to provide them with appropriate aesthetics, texture, pH, color, and smell as well as to fulfill the cosmetic claims for products.

5. Although color additives are not classified as active ingredients, they are still subject to a stricter regulation in the US.

6. Active ingredients deliver the claimed therapeutic action and have an effect on the human body, i.e., to prevent and/or treat a disease.

7. Active ingredients for cosmetic products are either listed in OTC monographs or are new ingredients.

Classification of Cosmetics and OTC Drug–Cosmetic Products

Cosmetics and OTC drug–cosmetic products can be classified in many ways. They can be classified based on the target groups, dosage forms, legal status, application surfaces, function, and numerous other ways. This section provides an overview of these classification systems (see Figure 1.4).

- **Target Groups**: A target group or target audience can be defined as a specific group of customers at whom a cosmetic product or OTC drug–cosmetic product is aimed. Target groups for cosmetics can include women, men, teenagers, and babies. The groups, such as women, can be further categorized into subcategories, such as pregnant women, African American women, women with sensitive skin, young women, and aging women.

- **Dosage Forms**: A dosage form is the final physical form of a mixture of ingredients that consumers can take in their hands, purchase, and use. The various dosage forms available for cosmetics and OTC drug–cosmetic products are discussed in Section 3 of this chapter.

- **Legal Status**: As discussed in Section 1, a product can be a cosmetic, a drug, or a combination of both, depending on the intended use. As a reminder, other product categories, such as cosmeceuticals, are not recognized by the FDA.
Application Surfaces: An application surface or area of application can be defined as a body surface to which cosmetics or OTC drug–cosmetic products are applied. These can include the skin of the face, lips, eyelids, body, and hands; hair on the scalp and body and eyelashes; teeth and oral cavity; and nails, among others.

Function: Cosmetics and OTC drug–cosmetic products can have a variety of functions. Examples include cleansing, which is the function of shampoos, bodywashes, hand soaps, and eye makeup removers; moisturizing, which is the function of facial creams, hand creams, body lotions, aftershave balms, and cuticle softeners; coloring, which is the function of many color cosmetics, such as lipstick, mascara, and blush; and protection, which is the function of sunscreens, diaper rash creams, and lip balms. Additionally, there are many other functions cosmetics and OTC drug–cosmetic products can fulfill. They will be further reviewed in the relevant chapters under the various product types.

Others: The cosmetic industry often classifies products into 5–6 different groups based on the combination of their function and application surface.
CHAPTER 1: GENERAL CONCEPTS

### Lip makeup products
- Lipstick, lip gloss, lip balm, and lip liner

### Eye makeup products
- Mascara, eye liner, eyebrow liner, eye shadow, and eye makeup remover

### Facial make-up products
- Facial foundation, blush, concealer

### Nail care products
- Nail polish, nail hardener, nail moisturizer, cuticle remover, artificial nail, and nail polish remover

### Skin care products
- Cleansers, moisturizers, products for special skin concerns, sunscreens, deodorants, and antiperspirants

### Hair care products
- Shampoo, conditioners, styling products, permanent waving and straightening products, and colors

### Oral and dental care products
- Toothpaste, mouthwash, and dental floss

### Other products
- Hair removal, baby care products, sunless tanners, and feminine hygiene products

**Figure 1.5** Major product categories in the cosmetic industry: (a) major categories of color cosmetics and (b) major categories of personal care products.

Popular categories include color cosmetics, skin care products, hair care products, oral care products, perfumes, and other products.

This textbook reviews color cosmetics in one chapter with the ultimate function of coloring. The various product types to be covered are shown in Figure 1.5a. Personal care products are broken down into various chapters based on the application surfaces and main functions (see Figure 1.5b).

### Major Ingredient Types in Cosmetics and OTC Drug–Cosmetic Products and Their Functions

**Cosmetic Ingredients**  ⚫ Since cosmetics do not treat any conditions or affect the structure of the skin, they do not contain active ingredients. Cosmetic products contain cosmetic ingredients only. ☑️ Since OTC drug–cosmetic products are used for the prevention, diagnosis, cure, or treatment of a disease; they contain active ingredients, in addition to the cosmetic ingredients. In these products, cosmetic ingredients are referred to as inactive ingredients.

⚫ Cosmetic ingredients are used in products to provide them with appropriate aesthetics, texture, pH, color, and smell as well as to fulfill the cosmetic
claims for products. They have a variety of functions in cosmetics and OTC drug–cosmetic products, including helping mix immiscible ingredients, stabilizing formulations, moisturizing the skin, adding luster to the hair, providing color to products, helping expel the content of aerosol cans, removing stain from the teeth, just to mention a few. A commonly used and practical way to classify ingredients is based on the functions of the ingredients. As many ingredients have multiple functions, they can belong to more than one group. This section is a part that reviews the most commonly used types of cosmetic ingredients (without completeness) and their main functions, including examples for each type of ingredient.

Abrasives The term “abrasive” refers to an ingredient that is capable of polishing or cleaning a harder surface by rubbing or grinding. Abrasives are solid particles and are generally used in toothpastes and skin care products, such as face, hand, foot, and body scrubs. Although the effect these ingredients provide is the same, the types used in oral and skin care products are different.

- In skin care formulations, abrasives provide an exfoliating effect, which means that they help rub off and peel the outer layer of the skin, known as the stratum corneum (SC). The skin has its own normal peeling process known as desquamation. However, in certain cases, it can be beneficial to help the skin peel off the dead cells from its surface.
- Examples for abrasives used in facial and body formulations include seeds of fruits, such as peach, apple, and apricot; nutshell, such as almond and walnut; grains, such as oats and wheat; synthetic components, such as polyethylene and polypropylene beads; nylon powder; synthetic waxes; and natural waxes, e.g., rice bran wax.
- Abrasives also contribute to the physical cleaning effect and stain removal of toothpastes as well as increase the gloss of the teeth. Abrasives in toothpastes are usually finely ground particles that will not hurt and wear away the enamel but are able to clean the teeth and remove discoloration to a certain extent.
- Examples for abrasives used in toothpastes include mineral powders, such as hydrated alumina, dehydrated silica, magnesium and calcium carbonate, dicalcium phosphate, and sodium bicarbonate.

Antioxidants Antioxidants, as their name implies, provide protection against oxidative reactions. This property is generally utilized to provide stability to cosmetic formulations and can also be used to slow down skin aging caused by various oxidative mechanisms. Based on these, antioxidants can be used to fulfill two different functions in cosmetics and OTC drug–cosmetic products.

- Antioxidants can prevent undesirable chemical changes (such as decomposition, rancidity, color change, and odor formation) within a formulation triggered by oxygen in the presence of light, heat, or metal ions. Therefore, they contribute to the stability of cosmetic products. These ingredients are found in the majority...
CHAPTER 1: GENERAL CONCEPTS

of cosmetics and OTC drug–cosmetic products, especially in those containing oils, fats, butters, and waxes since these ingredients are generally more sensitive to oxidation reactions than other ingredients.

- Examples for antioxidants used as stabilizers in cosmetic products include mainly synthetic compounds, such as butylated hydroxytoluene (generally referred to as “BHT”), butylated hydroxyanisole (generally referred to as “BHA”), and propyl gallate.

- In addition, they are also beneficial for the users’ skin since they fight against free radicals in the skin. It is known that oxidative stress initiated by free radicals accelerate skin aging and contribute to the formation of lines and wrinkles, pigmentation, or even malignant processes. We have natural antioxidants and defense mechanisms in our skin to neutralize free radicals; however, applying antioxidants helps inactivate these reactive molecules and prevent symptoms related to sunlight-induced skin aging. Antioxidants for this purpose are often found in skin moisturizing products.

- Examples for skin antioxidants include vitamins, such as vitamin A, vitamin C (ascorbic acid), and vitamin E (tocopherol), as well as natural extracts, isoflavones and polyphenols.

**Chelating Agents**

Chelating agents are molecules with a specific three-dimensional structure that are able to complex with metal ions. Metallic impurities can come from many different sources, including cosmetic ingredients, water system, metallic equipment, and storage containers. If not deactivated, they can deteriorate cosmetic products by reducing clarity, compromising fragrance integrity, and causing rancidity. Chelating agents can help stabilize cosmetics and prevent their deterioration by catching (sequestering) metal ions.

- Examples for chelating agents used in cosmetics and OTC drug–cosmetic products include ethylenediaminetetraacetic acid (generally referred to as “EDTA”), its derivatives, including disodium and tetradsodium EDTA; phosphoric and phosphonic acid derivatives; as well as citric acid and its derivatives.

**DID YOU KNOW?**

The word “chelate” comes from the Greek word for crab’s claw. It refers to a three-dimensional, pincer-like structure of the chelating molecule and the metal ion. The chelating agent seizes the metal ion as if with a claw and keeps it from reacting with other substances.
SECTION 2: CLASSIFICATION OF COSMETICS

Color Additives  Color additives add color to cosmetic and OTC drug–cosmetic products, making them attractive, appealing, appetizing, and informative. Although color additives are not classified as active ingredients, they are still subject to a stricter regulation in the US. Therefore, they are discussed here in more detail.

DID YOU KNOW?

The terms “colorant,” “coloring agent,” and “color additive” can be used interchangeably; however, the official term used by the FDA is “color additive.”

According to the FD&C Act, a color additive is: “Any material that is a dye, pigment, or other substance [...] when added or applied to a food, drug, or cosmetic or to the human body or any part thereof, is capable of imparting a color thereto.” Based on the properties and composition of these ingredients, several subclasses can be distinguished.

- A dye is a chemical compound that is soluble in the particular solvent in which it is dispersed (e.g., oil or water). Examples include indigo and Green 3.
- A pigment is a component that is insoluble in the particular solvent in which it is dispersed. An example is black iron oxide.
- A lake is a water-insoluble pigment formed by chemically reacting dyes with a substratum, for example, aluminum, calcium, or barium. These pigments are widely used in lipsticks and nail lacquers. An example is Yellow 5 Al Lake.

As mentioned previously, color additives are subject to a strict system of approval under US law. Color additives (except for coal-tar hair dyes) must go through a pre-market approval process before they may be used in cosmetics (see more information on coal-tar hair dyes in Chapter 5). There is a list available for approved color additives, otherwise known as the positive list. The list specifies areas to which color additives can be applied, as well as limitations, restrictions, and comments on their use. It may happen that a color additive is approved for cosmetic use in general, but not for the eye area. Product manufacturers can only use color additives that have been approved by the FDA for intended uses stated in the regulations that pertain to them. The reason for this approval is that many color additives can cause skin irritation and allergic-type reactions; therefore, not all of them can be used in cosmetics, and there are some restrictions even for approved ingredients.
CHAPTER 1: GENERAL CONCEPTS

DID YOU KNOW?

The FDA has not approved any tattoo pigments for injection into the skin. This applies to all tattoo pigments, including those used for ultraviolet (UV) and glow-in-the-dark tattoos. Many pigments used in tattoo inks are industrial-grade colors suitable for printers’ ink or automobile paint.

In addition to premarket approval, a number of color additives must be batch certified in the US. Based on whether a color additive has to be certified or not, the FD&C Act classifies color additives into two main categories: those subject to certification (called certifiable color additives) and those exempt from certification. In general, batch certification is required when the composition of a color additive needs to be controlled to protect public health. Some color additives may contain impurities of toxicological concern. For ingredients that are certifiable, the law requires each and every batch of these color additives to be tested and certified by the FDA before it can be used in cosmetics.

- **Colors subject to certification** include synthetic organic dyes, lakes, or pigments. These ingredients have either three-part names, including a prefix, a color, and a number (such as FD&C Yellow No. 5), or a shorter name without a prefix (such as Yellow 5).
- **Colors exempt from certification** are generally obtained from mineral, plant, or animal sources. They usually have simple or chemical names (such as bismuth citrate, caramel, dihydroxyacetone, lead acetate, and titanium dioxide).

**Flavoring Agents** A flavor is generally described as the sensory impression of food or other substance and is determined by the texture, taste, and smell of a product. Flavoring agents provide a characteristic taste and/or smell to products. In addition, they can also mask bad taste. Overall, they contribute to product acceptance. Flavoring ingredients are primarily used in products that come into contact with the taste buds, including lip care formulations, such as lipstick, as well as dental and oral care products, such as toothpaste.

- Examples for flavoring agents used in cosmetics and OTC drug–cosmetic products include ingredients providing natural flavors, such as peppermint, wintergreen, menthol, eucalyptol, strawberry, and banana, and those providing artificial flavor, such as chocolate, bubble gum, and punch.

**Fragrances** Fragrances are natural or synthetic compounds with a characteristic smell that are added to cosmetics and OTC drug–cosmetic products to create an aesthetic impression for consumers and make them feel more attractive due to the nice smell. Fragrances can also be added to cosmetics and OTC drug–cosmetic products
to mask the undesirable odor of one or more of the raw ingredients. Unlike perfumes, which are hydroalcoholic solutions with a high fragrance content sprayed on the skin to transit a pleasant redolence to the user, personal and cosmetic care fragrances have a lower perfume content and are generally used in makeup products and skin and hair care formulations to increase product acceptance and mask the natural smell of the ingredients.

- Examples for fragrances used in cosmetics and OTC drug–cosmetic products include natural components, such as essential oils obtained from different parts of flowers, fruits, roots, leaves, and seeds. They may also be obtained from animal glands and organs. Another class includes synthetic fragrance components such as linalool and citronellol. Nowadays, mainly synthetic fragrances are used to ensure reproducibility. In addition, synthetic fragrances can be stronger, longer lasting, more complex, easier to manufacture and sophisticated, more reproducible from lot to lot, and less expensive than natural fragrances.

Moisturizers

The term “moisturizer” is an umbrella term used to describe ingredients that add moisture to the skin and help retain moisture in the skin. They make the skin feel softer and smoother and reduce roughness, cracking, and irritation. These ingredients are used in many of today’s formulations either as a main component of a formulation, for example, in a daily facial moisturizer, or as ingredients that provide additional benefits, for example, in a nail polish remover. Currently, four subclasses of moisturizers are distinguished (see more detail on the various types of moisturizers in Section 3 of Chapter 3).

- Humectants are hygroscopic ingredients. In general, they can serve two functions in cosmetics and OTC drug–cosmetic products, which are the following:
  - They can contribute to skin hydration by drawing water from the deeper layers of the epidermis and dermis to the outer layer of the skin (SC). Examples for humectants used for their moisturization properties include glycerin, sorbitol, urea, and propylene glycol.
  - In addition, they inhibit water evaporation from cosmetic products, i.e., provide protection against drying out. Typically, sorbitol and glycerin are used for this purpose.

- Emollients replenish oils and lipids in the skin. They soften and smooth the skin by filling void spaces on the skin surface and replacing lost lipids in the SC. They also provide protection and lubrication on the skin surface, minimize chafing, and enhance the skin’s aesthetic properties.
  - Examples for emollients used in cosmetics and OTC drug–cosmetic products include vegetable oils; seed and nut oils; fruit butters; lanolin; synthetic esters of fatty alcohols and fatty acids, such as isopropyl palmitate and glyceryl stearate; polymers, such as polyquaterniums; hydrocarbons, such as mineral oil and paraffin; siloxanes, such as dimethicone and cyclopentasiloxane; and many others.
Occlusives are hydrophobic in nature and form a water-repellent layer over the skin. It physically blocks, or at least retards, water loss through the skin.

Examples for occlusives used in cosmetics include hydrocarbon oils and waxes, such as petrolatum, mineral oil, paraffin, carnauba, and candelilla wax; silicone oils, such as dimethicone; vegetable oils and animal fats; fatty acids, such as stearic acid; fatty alcohols, such as cetyl alcohol; and many other ingredients.

Enhancers of the skin barrier (otherwise known as skin rejuvenators) help restore, protect, and enhance the skin’s barrier function. Additionally, they create a film over the skin surface that aesthetically smoothens the skin and stretches out fine lines.

Examples for enhancers of the skin barrier used in cosmetics include proteins, such as collagen, keratin, and elastin.

As the mechanism of action is different for the various moisturizers, they are generally used in combination with each other to provide tailored benefits for consumers.

pH Buffers The pH buffers can change the pH of cosmetics and OTC drug–cosmetic formulations. pH adjustment may be necessary in formulations for many reasons. Examples include matching the formulation’s pH with that of the application surface, stabilizing formulations since certain ingredients are stable at specific pH values only, and thickening formulations as certain thickeners must be neutralized in order to achieve optimum viscosity. An example for these types of thickeners is the carbomers.

Examples for pH buffers used in cosmetics and OTC drug–cosmetic products include citric acid and lactic acid as acidic ingredients as well as sodium hydroxide and the commonly used triethanolamine as alkaline ingredients.

Plasticizers Plasticizers are ingredients that can soften films and impart flexibility to films, such as nail polish film or hair spray film, as the film dries. Often, the developing film is very rigid and brittle, which makes nail polish sensitive to chipping and cracking or hair spray film stiff and brittle. Plasticizers can help prevent these undesirable effects. Plasticizers are often used in nail polishes, nail hardeners, sunscreens, and film-former-based hair styling products.

Examples for plasticizers used in nail polishes include camphor, castor oil, glyceryl tribenzoate, triphenyl phosphate, citrate esters, and acetyl tributyl citrate, among others. In film-forming ingredient-based hair styling products, mainly mineral oil, dimethicone, and castor oil are used.
DID YOU KNOW?

Plasticizers are added to hard, brittle plastics to make them more flexible. Many cosmetic packaging materials, e.g., shower gel containers, liquid soap containers, and toothpaste tubes, also contain plasticizers, so that we are able to squeeze the bottle and get a small amount of it out of the container. If no plasticizers were added to these plastics, they would be too hard and easy to break.

Preservatives  Preservatives are used to prevent undesirable growth of molds, yeast, and bacteria in liquid, semisolid, and powder products. Their use is especially important in water-based products since water provides an ideal environment for microbial growth. The mechanism of action and range of efficacy usually vary among the different types of preservatives. Therefore, they are generally used in combination with each other to provide protection against a wide variety of microorganisms.

- Examples for preservatives used in cosmetics and OTC drug–cosmetic products include parabens, such as methylparaben and propylparaben; formaldehyde donors, such as DMDM hydantoin, imidazolidinyl urea, and glutaraldehyde; cationic surfactants (generally referred to as “quats”), such as benzalkonium chloride and benzethonium chloride; alcohols, such as ethanol and benzyl alcohol; phenol derivatives, such as phenoxyethanol; isothiazolones, such as methylchloroisothiazolinone; and other components, such as sorbic acid.

Propellants  Propellants are added to aerosol formulations to maintain a suitable pressure within the aerosol can and expel the content of the container when the valve is open. They are usually compressed or liquefied gases. Propellants are used in aerosol products, such as shaving creams, hair sprays, antiperspirants, and sunscreen products, among others.

- Examples for propellants used in cosmetics and OTC drug–cosmetic products include isopentane (liquefied gas), butane, isobutane, and propane (compressed gases).

Solvents  Solvents are important parts of most cosmetics and OTC drug–cosmetic formulations. They are typically liquids used to dissolve solid ingredients, mix with liquids, provide a vehicle for formulations, and contribute to the texture of products. Solvents can aid in the development of body lotions, facials creams, foundations, nail polish, hair spray, sunscreens, hand sanitizer, and many other products. They can contribute to the stability of formulations, regulate evaporation rate, provide a cooling
effect, aid in product application, modify the skin feel, modify the viscosity, influence
the film-forming properties, and have many other functions.

The solubility of an ingredient in a given solvent is largely a function of the polarity
of the solvent. Solvents work under the general rule of like dissolves like. The term
“like” refers to the overall polarity of the solvent molecule (whether polar or nonpo-
lar) and the overall polarity of the solute (i.e., ingredient to be dissolved). Based on the
dielectric constant, which refers to polarity, solvents are typically broadly classified
into three categories: polar, semi-polar, and non-polar solvents.

- **Polar solvents** contain strong dipolar molecules and exhibit hydrogen-bonding
  properties. Therefore, their dielectric constant is high. Polar solvents generally
dissolve polar solutes.
  - Typical polar solvents used in cosmetics and OTC drug–cosmetic products
    include water and glycols, such as glycerin and propylene glycol.

- **Semi-polar solvents** are also made up of strong dipolar molecules; however,
  they do not form hydrogen bonds. Semipolar solvents are capable of dissolv-
ing both polar and non-polar substances. Therefore, they can serve as a medium
for a multicomponent homogeneous system containing polar and non-polar sol-
vents.
  - Examples for semipolar solvents used in cosmetics and OTC drug–cosmetic
    products include alcohols, such as ethanol and isopropyl alcohol; ketones,
    such as acetone; and esters, such as ethyl acetate.

- **Non-polar solvents** contain molecules that have only a small or no dipolar char-
  acter (i.e., their dielectric constant is low). They dissolve non-polar molecules.
  - Examples for non-polar solvents used in cosmetics and OTC drug–cosmetic
    products include oils, such as mineral oil, petrolatum, sunflower oil, almond
    oil; silicone oils; hexane; toluene; and dimethyl ether.

This widely used classification for solvents is not exclusive. There are many sol-
vents that can fit into more than one of these broad categories. For example, glycerin
can be considered both polar and semi-polar although it can form hydrogen bonds.

Solvent selection for cosmetics and OTC drug–cosmetic products typically
depends on the types of ingredients in the formulation, types of dosage form, and
compatibility with the application surface. For example, nail polish formulas usually
contain semipolar solvents, such as ethyl acetate and isopropyl alcohol, since the
resins used as film-formers are only soluble in these solvents. However, these
solvents are not used for sunscreens as sunscreen ingredients are not soluble in these
solvents, and they could also irritate the skin. Many organic UV filters are oil-soluble
crystalline solids, which need to be dissolved in oils. If the solvent properties of the
oil phase are poor, the filters can recrystallize during storage, dramatically reducing
the efficacy. See more examples for solvents in the individual chapters for various
products.
Surfactants

Surfactants, also known as surface active ingredients, are the most widely used ingredients in cosmetics and OTC drug–cosmetic products. They have a very unique chemical structure, including both a hydrophilic (i.e., water loving) and a hydrophobic (i.e., oil loving) portion (depicted in Figure 1.6), which enables them to be dissolved both in water and in oil. Surfactants can lower the surface tension between two liquids or between a liquid and a solid, making them suitable for many applications. They contribute to the formulation, stability, and applicability of personal care and cosmetic products. They can fulfill a variety of functions in cosmetics and OTC drug–cosmetic products, including emulsification (they help two immiscible phases, e.g., water and oil, mix with each other to form an emulsion), solubilization, cleansing, foaming, foam boosting, wetting, antifoaming, conditioning, preserving, stabilizing, controlling viscosity, and many others.

![Figure 1.6](image)

**Figure 1.6** The basic structure of a surfactant molecule.

Surfactants can be classified based on their hydrophobic chain into hydrocarbon and silicone surfactants. A more general classification is based on the charge of their hydrophilic part, and the four subtypes are anionic, cationic, amphoteric, and non-ionic surfactants.

- **Anionic surfactants** contain a negative charge in their hydrophilic head. Anionic surfactants are typically utilized for their foaming and excellent cleaning properties. Their major drawback is the irritating potential, especially for sulfates, which may cause concerns for many consumers.
  - Examples for anionic surfactants used in cosmetics and OTC drug–cosmetic products include carboxylic acid compounds, such as stearic acid; soaps, such as triethanolamine stearate and potassium laurate; sulfates, such as sodium lauryl sulfate, ammonium lauryl sulfate, and sodium laureth sulfate; sulfonates, including taurates, isothionates, and olefin sulfonates; and sulfosuccinates, such as disodium laureth sulfosuccinate.

- **Cationic surfactants** contain a positive charge in their hydrophilic head. They represent the most powerful conditioning agents for the skin and hair. As the
Overall surface charge of the skin and hair is negative, cationic surfactants are electrostatically attracted to these negative sites.

- Examples for cationic surfactants used in cosmetics and OTC drug–cosmetic products include amines and their derivatives and the most frequently used quaternized ammonium compounds (often referred to as “quats”), such as cetrimonium chloride, stearalkonium chloride and benzalkonium chloride, and quaternium and polyquaternium molecules.

**Amphoteric surfactants** have both a negative and a positive charge in their hydrophilic head. They have good cleansing, bactericidal, bacteriostatic, lathering, and softening properties and are able to stabilize and induce foam formation. Therefore, they are used in shampoos, baby products, and aerosols.

- Examples for amphoteric surfactants used in cosmetics and OTC drug–cosmetic products include betaines, such as coco betaine, lauryl betaine, cocamidopropyl betaine, and hydroxysultaines.

**Nonionic surfactants** do not dissociate into ions, and their hydrophilic head does not carry any charge. Their surface activity is due to the alcohol and/or ethylene oxide groups. They are the most frequently used surfactants in cosmetics and OTC drug–cosmetic products. Their application areas include emulsion stabilization, conditioning, and solubilization. Their advantages over other types include independency from pH and the presence of electrolytes as well as low irritation potential and compatibility with other types.

- Examples for nonionic surfactants used in cosmetics and OTC drug–cosmetic products include glycol and glycerol esters, such as glyceryl monostearate; sorbitan esters, such as sorbitan stearate and sorbitan palmitate; polysorbates (otherwise known as ethoxylated sorbitan esters), such as polysorbate 20; fatty alcohols, such as cetyl alcohol and stearyl alcohol; polyoxyethylene–polyoxypropylene block copolymers (otherwise known as poloxamers), such as Poloxamer 407; amine oxides, such as cocamine oxide and cocamidopropylamine oxide; alkanolamides, such as cocamide monoethanolamine (MEA) and diethanolamine (DEA); alkylglucosides, such as lauryl glucoside; and many others.

Surfactants are typically characterized by their HLB numbers. The abbreviation “HLB” stands for hydrophile–lipophile balance. HLB is an empirical expression for the relationship of the hydrophilic and hydrophobic groups of a surfactant. The HLB system uses a scale of 1–20 based on the affinity of the surfactant to oil and water; the higher the HLB value, the more water soluble the surfactant. In general, emulsifiers with HLB values of 1–3 are antifoaming agents, those with values of 4–6 are water-in-oil (W/O) emulsifiers, those with values of 7–9 are wetting agents, those with values of 8–18 are oil-in-water (O/W) emulsifiers, those with values of 13–15 are cleansing agents, and those with values of 10–18 are solubilizing agents.
DID YOU KNOW?

Based on the cleansing and foaming properties, surfactants can be divided into primary and secondary surfactants (the latter are also known as co-surfactants). The main function of primary surfactants is cleansing and foaming. Co-surfactants are used to reduce irritation and drying caused by primary surfactants. Additionally, some co-surfactants also have conditioning effects. Therefore, many skin and hair cleansing products contain a mixture of primary and secondary surfactants.

Sweeteners  Sweeteners provide a sweet flavor and contribute to product acceptance in cosmetics and OTC drug–cosmetic products that come in direct contact with the taste buds. These products include toothpastes, mouthwashes, lipsticks, lip balms, and lip glosses. Sweeteners are generally categorized into two major groups: true sweeteners (also known as no-calorie sweeteners) that do not provide any calories, and low-calorie sweeteners that add some calories to products. They are usually used in combination with flavors as the combination of flavors and sweeteners provides an acceptable and attractive taste for the formulations.

- Examples for no-calorie sweeteners used in cosmetics and OTC drug–cosmetic products include sodium saccharin, acesulfame, aspartame, sucralose, and stevia, and examples for low-calorie sweeteners include xylitol, mannitol, and sorbitol.

DID YOU KNOW?

Most artificial sweeteners are not sugars; only sorbitol and xylitol are sugar derivatives, i.e., sugar alcohols. However, these molecules are still able to provide an intensive sweet taste ranging from 10 to 100 times sweeter than table sugar. For example, sodium saccharine is 700 times sweeter than table sugar. We can find these components in gums and diet beverages that have a sweet taste but provide a low- or no-calorie intake. An important property of these ingredients is that they do not promote the growth of bacteria that causes cavities (i.e., Streptococcus mutans).

Thickeners  Thickeners are ingredients that can increase the viscosity of cosmetics and OTC drug–cosmetic products. They also improve stability, modify appearance and products aesthetics, improve applicability, and modify the rheology of a product. Thickeners can also be used to build viscosity in suspensions and act as suspending agents, for example, in nail polish formulations.
CHAPTER 1: GENERAL CONCEPTS

We generally differentiate between viscosity-increasing agents for aqueous systems, which increase the viscosity of the aqueous (water) phase, such as the water phase of an O/W emulsion, and for nonaqueous systems, which increase the thickness of the oil phase of cosmetic products, such as the oil phase of a W/O emulsion.

- Examples for water-based thickeners include gums, such as xanthan gum and guar gum; cellulose and its derivatives, such as hydroxyethyl cellulose; hydrophilic clays, such as hectorites, bentonites, and magnesium aluminum silicates; polyethylene glycols (PEGs), such as PEG 200; and synthetic polymers, such as carbomers; and also sodium chloride. Examples for non-water-based systems include waxes, such as carnauba wax; long-chain alcohols, such as cetyl alcohol; organoclays; fumed silica; synthetic polymers; and polyethylenes, among others.

For the selection of thickeners, a variety of factors should be taken into consideration, including the product’s use, application surface, compatibility with other ingredients in the formula, pH (certain thickeners, e.g., carbomers, are alkali swellable, and they need an alkaline pH to reach optimum viscosity; therefore, they cannot be used in an acidic environment), clarity, the presence of electrolytes, temperature during processing (waxes have to be melted in order to be mixed with oils; if a product is made without heating, waxes cannot be used), and shear during processing (some ingredients, such as carbomer, require shear in order to be activated and gain optimum viscosity, while others may be sensitive for shearing, such as fumed silica).

DID YOU KNOW?

Separation of emulsions and sedimentation of suspensions can be described with the following equation, called Stokes’ law:

\[ V = \frac{2r^2g(D_1 - D_2)}{9\mu} \]

where \( V \) is the particle’s settling velocity (m/s), \( r \) is the radius of the particle, \( g \) is the gravitational acceleration (m/s²), \( D_1 \) is the density of the particles (kg/m³), \( D_2 \) is the density of the fluid (kg/m³), and \( \mu \) is the viscosity of the fluid (Pa·s). It is obvious from the equation that the higher the viscosity, the lower the settling velocity. Therefore, an emulsion or suspension will be more stable if it has a higher viscosity. An essential role in the formulation of emulsions and suspensions is to have a slow settling velocity. This is one of the main reasons for using thickeners in the formulations.

Active Ingredients  As discussed previously, OTC drug–cosmetic combination products also contain active ingredients. Active ingredients deliver the claimed
therapeutic action and have an effect on the human body, i.e., to prevent and/or treat a disease.

Active ingredients for cosmetic products are either listed in OTC monographs or are new ingredients. OTC monographs can be described as a “recipe book” that tells formulators what ingredients and in what concentration can be used. Active ingredients are broken down into categories and characterized together in the monographs. The monographs also describe what types of formulations an ingredient can be used for and also provide information on claims and labeling. For some product types, such as sunscreens, testing is described as well. OTC monographs define the safety, effectiveness, and labeling of all OTC active ingredients. They are continually updated by adding, changing, and removing ingredients, labeling, and other pertinent information, as needed.

The OTC monograph system was set up in 1972 with the FDA’s OTC Drug Review. The Drug Review is an ongoing process by which the safety and efficacy of OTC ingredients are assessed. An expert advisory panel reviews the data relating to claims and active ingredients for different therapeutic classes. The panel recommendations become mandated in an official OTC monograph through a three-step public rule-making process (see Figure 1.7).10

![Figure 1.7 The three-step OTC monograph process.](image)

- **Step 1:** In this step, the panel reviews active ingredients to determine whether they could be generally recognized as safe and effective for use in self-treatment. Panel reports are published in the Federal Register as an advanced notice of proposed rulemaking (ANPR). The ingredients in this phase are classified into one of these three categories:
  - **Category I:** Generally recognized as safe and effective for the claimed therapeutic indication (GRASE).
  - **Category II:** Not generally recognized as safe and effective or unacceptable indications (not GRASE).
  - **Category III:** Insufficient data available to permit final classification.
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- **Step 2:** Following FDA review and public comment, a tentative final monograph (TFM) is issued by the FDA and published in the Federal Register, proposing approved ingredients, uses, doses, required warning, and appropriate claims.

- **Step 3:** The final step is the implementation of the final monograph (FM). The monographs establish conditions under which certain OTC drug products are generally recognized as safe and effective. FMs are also published in the Federal Register.

If an OTC active ingredient does not have an FM, it means that there is not enough data on its safety and effectiveness to make a final decision about the ingredient. Since TMFs are in place for all categories of OTC drugs, in such cases, formulators should follow the guidelines of the TMFs. This is the case with many antimicrobial ingredients used in hand sanitizers.

If a company wishes to formulate an OTC drug–cosmetic product and use an active ingredient, it has several options to choose from, including the following:

- If the active ingredient **can be found in an FM**, the company can make and market the OTC product using the ingredient in its approved concentration for its approved indication. No FDA preapproval is necessary for this to occur. The OTC monograph system enables quick entry of conforming products to the marketplace.

- If the active ingredient cannot be found in any FMs, but **can be found in a TFM**, the company can use the ingredient based on the TFM. It should kept in mind that no final decision has yet been made on the status of the active ingredient, and it may change in the future. Therefore, it should regularly check the actual status of the ingredient.

- If the active ingredient **cannot be found in any OTC monographs**, it must undergo a separate review and approval; it is referred to as the New Drug Application (NDA). The company has to submit information on the safety and efficacy of the active ingredient with regard to the particular OTC drug–cosmetic product.

- If the active ingredient **can be found in an OTC monograph** (either a TFM or an FM); however, the indication for which the company wants to use the active ingredient **cannot be found**, and it must also undergo the NDA process (similar to the previous situation).

- A company may also **petition to change** an FM to include additional ingredients or to modify current labeling practice. In this case, it has to submit information on the safety and efficacy of the active ingredient. It cannot market the product with the new condition (e.g., higher dose) until the FM is amended.

Now, let us review the major active ingredient types (without completeness) that can be found in various types of OTC drug–cosmetic products.
SECTION 2: CLASSIFICATION OF COSMETICS

FYI

The electronic Code of Federal Regulations (eCFR) and OTC monographs are freely accessible for everyone. For more information, visit www.ecfr.gov and select Title 21 (Foods and Drugs).

Anti-Acne Ingredients  Acne is a complex skin disorder that develops when the hair follicles become plugged with oil and dead skin cells (see more information in Section 4 of Chapter 3). Acne most commonly occurs on the face, neck, back, and chest. Bacteria can grow in this plug and cause inflammation. Acne symptoms may vary from invisible clogged pores, through small, hardly noticeable clogged pores with a small white or black head, to red, enlarged, inflamed, and painful lesions, including papules, pustules, nodules, or cysts (depending on the severity).

Anti-acne ingredients are listed in the OTC monograph\textsuperscript{11} for topical antimicrobial drugs. The listed ingredients have abrasive, exfoliating (peeling), and antiseptic effects to remove the excess amount of oil and peel the skin. These ingredients can be found in skin care products, such as facial washes, toners, and moisturizers, as well as in makeup products, such as concealers.

- Examples for FDA-approved anti-acne ingredients used in the topical treatment of mild acne include benzoyl peroxide (in 2.5–10%), salicylic acid (in 0.5–2%), sulfur (in 3–10%), and resorcinol (in 2% when combined with sulfur).

Anticaries Ingredients  Caries (otherwise known as tooth decay or cavities) is characterized by brown spots or holes on the chewing surface of the teeth. Cavities usually do not hurt, unless they grow very large and affect the nerves or cause a tooth fracture. However, untreated tooth decay can destroy the inside of the tooth (pulp), which can lead to tooth loss (more information on cavities can be found in Chapter 6).

Anticaries ingredients are listed in the OTC monograph\textsuperscript{12} for anticavities drugs. These ingredients are used to prevent caries; strengthen the tooth enamel and slow down the formation of an invisible, sticky film (called plaque) that leads to caries formation; as well as restore and harden the teeth. These ingredients are available in all types of oral care products, including toothpaste, toothpaste gel, and mouthwash.

- Examples for FDA-approved anticaries ingredients used in OTC drug–cosmetic products include fluoride components, such as sodium monofluorophosphate, sodium fluoride, and stannous fluoride. Concentrations are specified for each ingredient for each product type, such as gel, paste, and mouthwash.

Antidandruff Ingredients  Dandruff is a common non-contagious condition of the scalp, characterized by an increased rate of shedding of dead cells from the scalp.
Although shedding of dead cells is continuous and imperceptible for most people, the rate of shedding is greatly accelerated in dandruff. The usual symptoms include white, oily-looking flakes on the hair and shoulders and itching. The causes of dandruff are thought to be the combination of an overproduction of skin oil and irritation from yeast called *Malassezia*.

Antidandruff ingredients are listed in the OTC monograph\(^\text{13}\) for miscellaneous external drug products. These ingredients have antimicrobial properties, and some of them also have exfoliating properties. Generally, they are formulated into shampoos.

- Examples for FDA-approved antidandruff ingredients used in OTC drug–cosmetic combination products include coal tar (in 0.5–5%), zinc pyrithione (in 0.3–2% when washed off), salicylic acid (in 1.8–3%), selenium sulfide (in 1%), and sulfur (in 2–5%).

**Antiperspirant Ingredients** Antiperspirants affect the function of the body by reducing the amount of sweat that reaches the skin surface and not just masking bad body odor as do deodorants do. Underarm odor is caused by the bacterial breakdown of sweat (see more detail in Section 6 of Chapter 3). Antiperspirants are listed in the OTC monograph\(^\text{14}\) for antiperspirant drug products.

- Examples for FDA-approved antiperspirant used in OTC drug–cosmetic products include aluminum chloride (up to 25%), aluminum chlorohydrate (up to 25%), aluminum sesquichlorohydrate (up to 25%), aluminum dichlorohydrate (up to 25%), and PEG and zirconium complexes, such as aluminum chlorohydrex PEG (up to 25%) and aluminum zirconium octachlorohydrate (up to 20%).

**Skin Protectant Ingredients** Skin protectant ingredients are listed in the OTC monograph\(^\text{15}\) for skin protectant drug products. This category includes several subcategories, such as astringents, lip protectant ingredients, and skin protectant ingredients.

- **Astringents** are applied to the skin or mucous membranes for a local and limited protein coagulant effect. They are commonly used in facial toners and aftershave solutions to tighten pores.

- Examples for FDA-approved astringents used in OTC drug–cosmetic products include aluminum acetate (in 0.13–0.5%), aluminum sulfate (in 46–63%), and witch hazel.

- **Lip protectants** temporarily prevent dryness and help relieve chapping of the exposed surfaces of the lips. They are traditionally called lip balms. Drying of the lips is a typical sign of dehydration. Ingredients used as lip protectants moisturize the lips as well as provide protection against further water loss.
Examples for FDA-approved lip protectants used in OTC drug–cosmetic products include allantoin (in 0.5–2%), cocoa butter (in 50–100%), dimethicone (in 1–30%), and petrolatum (in 30–100%), among many others.

**Skin protectants** temporarily protect injured or exposed skin or mucous membrane surfaces from harmful or annoying stimuli. In addition, they may provide relief to such surfaces. Skin protectants are usually formulated as lotions, creams, and ointments. Examples for skin protectants are the same as those for lip protectants.

**Sunscreens** Sunscreens (also known as UV filters) protect the skin from the harmful radiation of the sun. Sunscreens are listed in the OTC monograph for sunscreen drug products. They can be formulated into a variety of products forms, including aerosol sprays, lotions, sticks, and gels (see more detail on this in Section 5 of Chapter 3).

UV filters protect the skin via two separate mechanisms: either reflecting sunlight (physical filters) or absorbing sunlight and converting it to heat (chemical filters). Currently, there are 16 UV filters listed in the OTC monograph.

Examples for FDA-approved sunscreen ingredients used in OTC drug–cosmetic products include physical filters, such as titanium dioxide (up to 25%) and zinc oxide (up to 25%), as well as chemical filters, such as avobenzone (up to 3%), octocrylene (up to 10%), and padimate O (up to 8%).

Cosmetics and OTC drug–cosmetic products can contain additional types of ingredients. The purpose of this section was to provide the readers with a general understanding of the major and commonly used minor ingredients types before moving on to discuss the various product categories. More information is provided on the ingredient types, their function, and characteristics in the individual chapters for the various products.

**GLOSSARY OF TERMS FOR SECTION 2**

**Abrasive**: An ingredient that is capable of polishing or cleaning a harder surface by rubbing or grinding.

**Active ingredient**: An ingredient in OTC drugs or prescription-only drugs that delivers the claimed therapeutic action.

**Antiacne ingredient**: An ingredient that has abrasive, exfoliating (peeling), and/or antiseptic effects and can treat acne skin.

**Anticaries ingredient**: An ingredient that can help prevent the formation of brown holes in the teeth (i.e., tooth decay), strengthen the tooth enamel, slow down plaque formation, and harden the teeth.

**Antidandruff ingredient**: An ingredient that has antimicrobial and exfoliating effect and can treat dandruff.
Antioxidant: An ingredient that provides protection against oxidative reactions.

Antiperspirant: An ingredient that can reduce the amount of sweat reaching the skin surface.

Application surface: A body surface to which cosmetics or OTC drug–cosmetic products are applied.

Astringent: An ingredient that can provide the mucous membranes with a local and limited protein coagulant effect.

Chelating agent: An ingredient that is able to complex with metal ions.

Color additive: An ingredient that adds color to a product, making it attractive, appealing, appetizing, and informative.

Cosmetic ingredient: An ingredient that is used in cosmetic products to provide them with appropriate aesthetics, texture, pH, color, and smell, as well as to fulfill cosmetic claims for products. OTC drug–cosmetic products also contain cosmetic ingredients that are called inactive ingredients in their case.

Dosage form: The final physical form of a mixture of ingredients that consumers can take in their hands, purchase, and use.

Flavoring agent: An ingredient that provides a characteristic taste and/or smell to a product.

Lip protectant: An ingredient that can temporarily help prevent lip dryness and help relieve chapped lips.

Moisturizer: An ingredient that adds moisture to the skin and help keep moisture in the skin.

pH buffer: An ingredient that can change or maintain the pH of a product.

Plasticizer: An ingredient that can soften films and impart flexibility to films.

Preservative: An ingredient that can prevent undesirable growth of molds, yeast, and bacteria in a product.

Propellant: An ingredient that is added to aerosol formulations to maintain a suitable pressure within the can and expel the content of the container.

Solvent: An ingredient that is used to dissolve solid ingredients, mix with liquids, provide a vehicle for formulations, and contribute to the texture of products.

Sunscreen: An ingredient that can provide protection to the skin against the harmful UV radiation.

Surfactant: A surface active ingredient that can lower the surface tension between two liquids or between a liquid and a solid.

Sweetener: An ingredient that provides a sweet flavor to a product.

Target group: A specific group of customers at whom a cosmetic product or OTC drug–cosmetic is aimed.

Thickener: An ingredient that can increase the viscosity of a product.
REVIEW QUESTIONS FOR SECTION 2

Multiple Choice Questions

1. Which of the following ingredients do OTC drug–cosmetic products contain?
   a) Cosmetic ingredients, which are called inactive ingredients
   b) Active ingredients
   c) A and B
   d) None of the above

2. The use of preservatives is extremely crucial in the case of ___-based formulations.
   a) Oil
   b) Water
   c) Preservative
   d) Silicone

3. Anionic surfactants are primarily used as ___ agents in cosmetic products.
   a) Cleansing
   b) Conditioning
   c) Flavoring
   d) Coloring

4. What does the abbreviation “HLB” refer to?
   a) An empirical expression for the relationship of hydrophilic and hydrophobic groups in surfactants.
   b) A type of certification that has to be received before selling color additives to customers.
   c) A type of antioxidant that is used in anti-aging products.
   d) An expression for the relationship of sedimentation rate of suspensions.

5. Who certifies certifiable color additives?
   a) WHO
   b) EPA
   c) FDA
   d) OTC

6. Why is batch certification necessary for certain color additives?
   a) To make sure that these color additives have a natural origin
   b) To certify that they can be used for tattoos
   c) To ensure that there are no impurities of toxicological concern
   d) To check whether they are soluble in water
7. Flavors and sweeteners are typically included in formulations that can come into contact with the ___.
   a) Eyes
   b) Hair
   c) Sweat glands
   d) Taste buds

8. OTC monographs contain ___ ingredients that can be used in OTC products ___ receiving an FDA premarket approval.
   a) Active/with
   b) Inactive/with
   c) Active/without
   d) Inactive/without

Matching

Match the terms in column A with their appropriate definition in column B.

<table>
<thead>
<tr>
<th>Column A</th>
<th>Column B</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Abrasives</td>
<td>A. Ingredients that are strictly regulated in the United States.</td>
</tr>
<tr>
<td>2. Antioxidants</td>
<td>B. Ingredients that bind to metal ions.</td>
</tr>
<tr>
<td>3. Antiperspirants</td>
<td>C. Ingredients that help adjust the pH of cosmetic formulations.</td>
</tr>
<tr>
<td>4. Astringents</td>
<td>D. Ingredients that help expel the contents of aerosol containers.</td>
</tr>
<tr>
<td>5. Chelating agents</td>
<td>E. Ingredients that make cleansing products, e.g., shampoo’s bubble.</td>
</tr>
<tr>
<td>6. Color additives</td>
<td>F. Ingredients that make films more flexible.</td>
</tr>
<tr>
<td>7. Moisturizers</td>
<td>G. Ingredients that make the skin softer and smoother.</td>
</tr>
<tr>
<td>8. pH buffers</td>
<td>H. Ingredients that prevent the growth of bacteria, molds, and yeast.</td>
</tr>
<tr>
<td>9. Plasticizers</td>
<td>I. Ingredients that provide a local and limited protein coagulant effect.</td>
</tr>
<tr>
<td>10. Preservatives</td>
<td>J. Ingredients that provide a sweet taste for formulations.</td>
</tr>
<tr>
<td>11. Propellants</td>
<td>K. Ingredients that provide a vehicle for formulations.</td>
</tr>
<tr>
<td>12. Solvents</td>
<td>L. Ingredients that provide protection against free radicals.</td>
</tr>
</tbody>
</table>
Matching

Match the terms in column A with their appropriate definition in column B.

<table>
<thead>
<tr>
<th>Column A</th>
<th>Column B</th>
</tr>
</thead>
<tbody>
<tr>
<td>13. Sunscreens</td>
<td>M. Ingredients that provide protection from the sun.</td>
</tr>
<tr>
<td>14. Surfactants</td>
<td>N. Ingredients that provide viscosity control for cosmetic formulations.</td>
</tr>
<tr>
<td>15. Sweeteners</td>
<td>O. Ingredients that reduce the amount of sweat.</td>
</tr>
<tr>
<td>16. Thickeners</td>
<td>P. Ingredients used in facial scrubs for their exfoliating effect.</td>
</tr>
</tbody>
</table>

REFERENCES

2. CFR Title 21 Part 70.3(f)
3. CFR Title 21 Part 71
5. FD&C Act Part 721(c)
CHAPTER 1: GENERAL CONCEPTS

6. CFR Title 21 Parts 70 and 80
11. CFR Title 21 Part 333.301–333.350
12. CFR Title 21 Part 355
13. CFR Title 21 Part 358.701–358.760
14. CFR Title 21 Part 350
15. CFR Title 21 Part 347
16. CFR Title 21 Part 352

SECTION 3: DOSAGE FORMS FOR COSMETICS AND OTC DRUG–COSMETIC PRODUCTS

LEARNING OBJECTIVES

Upon completion of this section, the reader will be able to

1. Define the following terms:

| Anhydrous Liquid dosage form | Hydroalcoholic Solid dosage form | Solution Semisolid dosage form | Dosage form Emulsion Gel Cap sleeve Stokes’ law |
| Anhydrous Liquid dosage form | Hydroalcoholic Solid dosage form | Solution Semisolid dosage form | Dosage form Emulsion Gel Cap sleeve Stokes’ law |
| Lotion | Lotion | Lotion | Lotion |
| Paste | Paste | Paste | Paste |
| Stick | Stick | Stick | Stick |
| Aqueous | Aqueous | Aqueous | Aqueous |

2. explain the concept of a dosage form;
3. differentiate between a solution and an emulsion;
4. distinguish between an emulsion and a suspension;
5. explain the difference between a lotion and a cream;
6. explain the difference between regular pastes and toothpastes;
7. discuss the advantages of gels when used as cosmetic products;
8. discuss the advantages of using sticks;
9. briefly discuss the main advantages and disadvantages of creams and ointments;
10. briefly discuss the importance of thickeners as it applies to suspensions;
11. briefly discuss the potential use of capsules as cosmetic products;
12. explain the concept of an aerosol product;
13. provide a few cosmetic and/or OTC drug–cosmetic examples for the following dosage forms: solution, cream, lotion, ointment, suspension, loose powder, pressed powder, capsule, gel, stick, aerosol, foam, and paste.

KEY CONCEPTS

1. Cosmetics and OTC drug–cosmetic products are available as hundreds of types of formulations, which can be broken down into some basic groups, called dosage forms, based on their physical and pharmaceutical properties.
2. A dosage form is defined as the final physical form of a mixture of chemical ingredients that consumers can take in their hands, purchase, and use as a cosmetic product or an OTC drug–cosmetic product.
3. Dosage forms can be classified based on their physical form as liquids, semisolids, and solids.
4. Liquid dosage forms available as cosmetics and OTC drug–cosmetic products include solutions, lotions, and suspensions.
5. Solid dosage forms available as cosmetics and OTC drug–cosmetic products include loose powders, pressed powders, sticks, and capsules.
6. Semisolid dosage forms available as cosmetics and OTC drug–cosmetic products include creams, ointments, pastes, and gels.

Cosmetics and OTC drug–cosmetic products are available as hundreds of types of formulations, such as a shower gel, baby powder, lipstick, bath bomb, liquid eyeliner, shaving foam, lip liner pencil, toothpaste, roll-on deodorant, and many others. However, all these different formulations can be broken down into some basic groups, called dosage forms, based on their physical and pharmaceutical properties. This section provides an overview of the most common dosage forms available for cosmetics and OTC drug–cosmetic products and their main characteristics. It also summarizes the main advantages and disadvantages of the different dosage forms and provides ideas on how and when the various dosage forms should be selected.
What Is a Dosage Form?

Before starting to discuss the different dosage forms, let us first understand what a dosage form is. **A dosage form is defined as the final physical form of a mixture of chemical ingredients** (cosmetic ingredients and/or active ingredients) **that consumers can take in their hands, purchase, and use as a cosmetic product or an OTC drug–cosmetic product.**

A relevant question would be: “Why are there dosage forms?” Cosmetic and/or active ingredients cannot be applied individually to the skin, hair, or mucous membranes; for example, consider a simple mouthwash. It is composed of at least 6–8 different ingredients. The consumer cannot just buy the individual ingredients and apply them one after another to mimic a mouthwash formulation. The ingredients have to be put into a form (a dosage form) that contains all ingredients in a specific ratio and can be applied to the oral mucous membrane.

**Dosage forms can be classified based on their physical form as liquids, semisolids, and solids.** Figure 1.8 illustrates the major cosmetic dosage form subclasses.

- If a dosage form is pourable and consists of liquid ingredients, it is classified as a **liquid** dosage form. These dosage forms cannot be directly taken into the hands as they would flow off the hands. **Liquid dosage forms available as cosmetics and OTC drug–cosmetic products include solutions, lotions, and suspensions.**

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**Figure 1.8** The major types of dosage forms and their subclasses typically used for cosmetic products.
If a dosage form consists of dry solid particles, mixed and/or pressed together, or waxy materials that are present in a solidified form having a characteristic shape, the dosage form is classified as a solid dosage form. **Solid dosage forms available as cosmetics and OTC drug–cosmetic products include loose powders, pressed powders, sticks, and capsules.**

If a dosage form has a consistency in between solid and liquid forms, it is classified as a semisolid dosage form. The difference is usually in the viscosity of these dosage forms. If a dosage form has a low viscosity, meaning that it can be easily poured and will quickly flow off the hands, it is a liquid. If it is more viscous, and more force is needed to dispense and apply it, it is a semisolid. **Semisolid dosage forms available as cosmetics and OTC drug–cosmetic products include creams, ointments, pastes, and gels.**

When selecting dosage forms for a product, a formulator has to take many factors into account. These include the properties of the ingredients used: whether they are water-soluble (hydrophilic) or oil-soluble (lipophilic), liquid or solid, and their compatibility with each other. Formulators must also consider the purpose of the product’s application and the application surface. For example, for the treatment of hair, an easily applicable and washable dosage form should be chosen, e.g., a lotion instead of a greasy ointment. If a longer-lasting effect is desired, such as for diaper rash formulations, the product type can be greasier and more water resistant, containing a higher amount of oils.

**Dosage Forms for Cosmetic Applications**

The FDA has a standard for drug dosage forms, including their definitions. This standard will be used as the basis of our discussion since the definition of a dosage form is the same regardless of the product’s status, i.e., a cosmetic or an OTC drug–cosmetic product. In addition, all dosage forms can be used for both cosmetics and OTC drug–cosmetic products.

**Solution** Solution is the simplest type of formulation. Solutions are liquids, they are pourable; they flow and conform to their container at room temperature. According to the FDA’s definition, “... a solution is a clear, homogeneous liquid dosage form that contains one or more chemical substances dissolved in a solvent or mixture of mutually miscible solvents.”

Solutions can be classified based on the types of solvent used. Three major types are usually distinguished, which are the following:

**Water-based** (i.e., aqueous) solutions contain water as the vehicle. Examples for water-based solutions include eye makeup remover, hand soap, and many shampoos.

**Hydroalcoholic** solutions contain a mixture of water and alcohol as the vehicle. Examples for hydroalcoholic solutions include hair spray, mouthwash, after-shave cologne, and facial toner.
Anhydrous (i.e., waterless) solutions contain ingredients other than water as the vehicle. The solvents can be organic solvent, such as for base coat or nail polish remover. Solvents can also be oily components, such as for bath oils or prewaxing oils.

A solution is considered a thermodynamically stable dosage form; it does not tend to change over time. The formulation of solutions is usually simple. Soluble solid ingredients are dissolved first, starting with those that need heating for the dissolution process. Smelly, easily evaporating ingredients are usually added at the end to prevent their loss from the product. Similarly, colored ingredients and color additives are also added at the end since they could make the completion of the dissolution process more difficult to detect.

DID YOU KNOW?

Cleansing wipes can also be classified as solutions since the dry, usually nonwoven clothes are soaked into a cleansing solution.

Emulsion

The majority of cosmetic raw materials are not miscible or just partially mixable with each other; in these cases, formulators have to choose a dosage form that can contain immiscible ingredients together. According to the FDA’s definition, “… an emulsion consists of a two-phase system comprised of at least two immiscible liquids, one of which is dispersed as droplets (this is usually referred to as the internal or dispersed phase) within the other liquid (otherwise known as the external or continuous phase), generally stabilized with one or more emulsifying agents.”

Based on this definition, there are three essential ingredients for an emulsion, namely an oil phase, a water phase, and an emulsifier. There are two main types of emulsions: O/W and W/O. In an O/W emulsion, oil is dispersed in water; the oil is present in the form of droplets, while the water is present as the outer (continuous) phase. The emulsifier molecules coat the surface of the oil droplets, making them more miscible with water and preventing them from flowing to the surface (see an O/W emulsion depicted in Figure 1.9). In an O/W emulsion, the surfactant molecules have their hydrophilic head groups oriented towards the continuous water phase and their hydrophobic tails facing the oil droplets.

Emulsions are the most widely used dosage forms in the cosmetic industry due to their advantages over other dosage forms. They have a unique texture and provide a nice skin feel, and they are used as vehicles to deliver both hydrophilic and hydrophobic ingredients.
Generally, O/W emulsions are chosen for applications that require a relatively small amount of fatty materials, such as for hair conditioners, shaving creams, or facial moisturizing creams.

On the other hand, W/O emulsions are preferred when a larger amount of oil is desired in the formulation. W/O emulsions are greasier, leave a longer-lasting residue, and are more water resistant (as they contain oils in the outer phase). Typical products for which W/O emulsions are preferred include diaper rash products, sunscreens, and barrier creams.

From a cosmetic perspective, water-in-silicon (W/Si) emulsions are also important. These formulations provide a unique, nongreasy skin feel and quick drying effect, leaving the skin smooth. Examples for such formulations include facial foundations, cream eyeshadows, and certain sunscreens.

In addition to the simple two-phase emulsions, more complex types may also be formed, such as water-in-oil-in-water (W/O/W) emulsions, which are basically an emulsion in an emulsion.

Emulsions are generally opaque formulations due to the size of the internal phase’s droplets. This white, creamy appearance is generally appealing to consumers. They are thermodynamically instable, which means that they tend to separate over time. As we know, water and oil do not mix. Emulsions incorporate these two ingredients using emulsifiers, which help keep the phases mixed in each other for a longer period of time. However, even with emulsifiers, the phases try to reach the state of lowest energy to be stable. According to Stokes’ law, the stability of emulsions can be increased by decreasing the droplet size of the internal phase (which can be achieved by intensive mixing); the densities of the two phases should be as close as possible.
usually, this factor cannot be modified since it depends on the types of ingredients used); and the viscosity of the continuous phase should be increased, which then can act as a barrier against merging of the internal phase’s droplets. In addition, proper selection of the emulsifiers’ type and amount used is an essential step, which should be performed according to the oil phase’s HLB need. Additionally, the final product should not be kept at high temperature, since high temperature affects the viscosity of formulations and the oxidation stability of oils and fats.

**DID YOU KNOW?**

The proportion of the phases does not necessarily correlate to the type of the emulsion. For example, a formulation that consists of 65% water phase and 35% oil phase does not necessarily mean that it is an O/W emulsion. The main factor that determines the type of an emulsion is the solubility of the emulsifier agents. According to Bancroft’s rule, “...the phase in which the emulsifier is most soluble becomes the continuous phase.” Therefore, water-soluble emulsifiers (with high HLB values) promote the formation of O/W emulsions, whereas oil-soluble emulsifiers (with low HLB values) promote the formation of W/O emulsions.

Based on their viscosity, usually two types of emulsions are distinguished for cosmetic applications, namely lotions and creams.

- **Lotions** are low-viscosity (thin) emulsions behaving as liquids; therefore, they can be poured from a bottle or pumped from a jar. They are designed to be applied without heavy rubbing. According to the FDA’s definition, “...a lotion is an emulsion, liquid dosage form.” Lotions contain a higher amount of water in the continuous phase than creams. Due to the higher amount of water phase, they are less greasy and easily washable. Lotions are often referred to as “milks” and “balms.” Examples for lotions include facial cleansing milks, liquid foundations, aftershave balms, and non-aerosol sunscreen sprays.

- **Creams** are high-viscosity (thicker), semisolid emulsions. According to the FDA’s definition, “...a cream is an emulsion usually containing > 20% water and volatiles and/or < 50% hydrocarbons, waxes, or polyols as the vehicle.” Since creams contain a higher amount of oil phase, they are generally more greasy, even the O/W types. Creams do not flow readily; therefore, they can be packed into a jar or a tube for dispensing. Examples for creams include facial moisturizing creams, leave-in hair conditioners, sunscreens, cream eyeshadows, and depilatory creams.

The conventional method of preparing a cosmetic emulsion is the hot method. It includes heating the two phases separately and, when both of their temperatures
are the same, mixing them together vigorously. Mixing should generally continue until the emulsion is cool to prevent immediate separation. Once cool, additional temperature- and shear-sensitive ingredients can be added and mixed into the emulsion.

Another method, known as the cold process, can also be used for certain emulsions. In this process, the phases can be mixed at room temperature without heating. The advantage of this technique is that it saves energy since no heating is needed, and also saves the processing time as all ingredients, including the temperature-sensitive ingredients, can be combined prior to mixing the two phases. However, it limits the types of thickeners that can be used for the formulations; for example, waxes cannot be used as they require heating.

DID YOU KNOW?

Foams can also be categorized as emulsions where the gas phase is dispersed in a liquid continuous medium.

**Ointment** Ointments are superthick semisolid products compared to lotions or creams. According to the FDA’s definition, “…an ointment is a semisolid dosage form, usually containing <20% water and volatiles and >50% hydrocarbons, waxes, or polyols as the vehicle. They are usually used topically for protection or as medicated skin products.”

Ointments have an occlusive nature and provide a seal over the skin. They can contain a small amount of water or can be anhydrous. In the case of anhydrous formulations, the chance for microbiological contamination is low, which is a distinct advantage. However, ointments have a less aesthetic appeal for skin care and dermatology products as they are oily, waxy, greasy, sticky, tacky, and heavy. They are advantageous for smaller skin areas that are extremely dry and need moisture retention, and for areas that are prone to friction from clothing and need protection. Ointments are often opaque and yellowish due to the high amount of oils. Due to the undesired skin feel, there are only a small number of cosmetic products formulated as ointments. Examples include some hair styling products, such as hair pomade; and diaper rash ointments.

The formulation steps for ointments depend on whether they contain water. If they contain water, they can be considered very thin W/O emulsions. These are processed with the hot method. If anhydrous, their formulation consists of mixing the oily ingredients until a homogeneous mixture develops. Heating may be needed.

**Paste** Pastes are very thick semisolid formulations that are difficult to apply and spread over the skin surface due to their high solid content. They are similar to
ointments but contain more solids and, therefore, are stiffer. According to the FDA’s definition, “… a paste is a semisolid dosage form that contains a large proportion (20–50%) of solids finely dispersed in a fatty vehicle. This dosage form is generally used for external application to the skin or mucous membranes.”

From a cosmetic perspective, pastes as dosage forms can be used as diaper rash treatment products. Additionally, toothpastes are also pastes that are meant to clean and/or polish the teeth. According to the FDA’s definition, “… a toothpaste is intended to clean and/or polish the teeth, and it may contain certain additional agents.” However, there is a huge difference between “regular” paste and toothpaste from the vehicle’s perspective. Regular pastes are anhydrous formulations, based on a fatty vehicle; therefore, they are highly adhesive to surfaces and hard to remove with water. Toothpastes, on the other hand, are water-based formulations that mix well with the saliva. If they were based on a fatty vehicle, their application would be uncomfortable.

**Suspension** A suspension is a dosage form for delivering insoluble solid ingredients in a liquid medium. According to the FDA’s definition, “… a suspension is a liquid dosage form that contains solid particles dispersed in a liquid vehicle.”

Based on the type of the liquid vehicle, usually three types of suspensions are distinguished, including the following:

- **Water-based** suspensions;
- **Hydroalcoholic** formulations, such as certain facial toners;
- **Anhydrous** formulations, such as silicone-based antiperspirant sprays, organic solvent-based nail polishes, and any liquid colored cosmetics containing pigments as color additives, such as mascara, liquid eyeliner, and lip gloss.

Suspensions, similar to emulsions, are thermodynamically unstable. The insoluble particles—due to gravitation—tend to sediment to the bottom of the container over time. The rate of sedimentation can be characterized by the Stokes’ equation that was discussed under emulsions. According to Stokes’ law, factors influencing the stability of suspensions include the viscosity of the liquid phase, difference in densities between the two phases, particle size of the insoluble particles, and gravitational acceleration. Of these factors, the viscosity of the liquid phase and particle size of the dispersed phase can be easily modified to increase suspension stability. Thickeners are essential parts of suspensions since they can increase viscosity and, therefore, slow down the rate of sedimentation of insoluble solid particles and increase the systems’ overall stability (see Figure 1.10). The smaller the particle size of the insoluble ingredient(s), the slower the sedimentation. Size reduction can be achieved by grinding the powders using a mortar and a pestle on a laboratory-scale basis or using mills on a larger scale.
Figure 1.10  Sedimentation of solid particles in a suspension over time: (a) if no thickeners are used, the insoluble solid particles sediment at the bottom of the container in a short period of time and (b) when thickeners are used, they can increase the viscosity of the liquid phase and keep the solid particles dispersed in the liquid medium, slowing down the rate of sedimentation.

The formulation of suspensions usually starts with the size reduction step as well as preparation of the thickener solution, which can be a lengthy procedure. After proper hydration and swelling of the thickener, other liquid ingredients can be mixed into the liquid phase. Finally, the solid particles are wetted and a concentrated slurry is made using a small portion of the liquid phase to get a smooth, uniform preparation. Additional liquid phase can be added after the mixture becomes uniform and no clumps or non-wetted powder aggregates are present.

DID YOU KNOW?
The labeling of certain facial toners, body toners, and eyeshadows indicates that the product should be shaken before use to activate the main ingredients. Usually, this description designates suspensions since suspensions sediment over time; therefore, shaking redisperses (“activates”) the insoluble powders.

DID YOU KNOW?
The major difference between a solution and a suspension is the type of solid ingredient dispersed in the liquid vehicle. Solutions contain soluble ingredients; therefore, they are clear formulations. Suspensions contain insoluble ingredients, which make the formulations cloudy.

**Powder (Including Loose and Pressed Powder)**  Powders are solid dosage forms. According to the FDA’s definition, “… a powder is an intimate mixture of dry, finely divided chemicals.”
Usually, two major types of powders are distinguished, namely loose and pressed powders.

- **Loose powders** are freely flowing mixtures of different dry solid chemicals. This dosage form is used for some makeup products, including mineral facial powders, blushes, and some eye shadows, as well as for baby powder and bath salts. Bath salts are usually grittier and have a larger particle size than other loose powders. The formulation of loose powders usually starts with grinding of the raw materials to provide a similar, fine particle size for them (unless they are purchased as a fine powder). After grinding, the ingredients are mixed together and then sieved before filling them into the container. Geometric dilution is used when blending two or more powder ingredients of unequal quantities. In this method, ingredients are mixed in approximately equal volumes. Geometric dilution provides uniform distribution for powders, which contain various powder ingredients in varying quantities.

- **Pressed powders** are made of a blend of freely flowing powders via compression. Pressed powders are popular for eyeshadows, facial powders, finishing powders, and blushes as well. Bath bombs are also examples for pressed powders, which are available in various shapes. The first steps of their formulation are similar to those of loose powders (grinding and mixing); however, instead of filling them into the container, they are pressed into shape. Today, a wide variety of shapes are available on the market, including rectangular, triangle, round, flower, heart, and many others. In the case of cosmetic formulations, it is usual that the powders are directly compressed into their final container (called a godet, i.e., an aluminum plate). Pressed powders usually contain binders, which keep the particles together and prevent breaking and crumbling upon shaking. Examples for binders include solid ingredients, such as zinc stearate, and starches, as well as liquids, such as isopropyl isostearate, triglyceride, and dimethicone.

**Capsule** According to the FDA’s definition, “…a capsule is a solid dosage form consisting of a shell and a filling. The shell is composed of a single sealed enclosure, or two halves that fit together and which are sometimes sealed with a band. Capsule shells may be made from gelatin, starch, or cellulose, or other suitable materials, may be soft or hard, and are filled with solid or liquid ingredients that can be poured or squeezed.”

From a cosmetic perspective, capsules are always soft gelatin capsules that contain an oily liquid ingredient inside. Examples for such products include bath oil beads and anti-aging serum capsules. Bath oil beads are used in the bathtub. Due to the gelatin, the capsules easily dissolve when they come into contact with bathwater and release their contents into the bathtub. Anti-aging serum capsules usually have a small tab that can be gently twisted or cut to open the capsule. Since soft capsules are easy to squeeze, the product can be get released the shell by gently squeezing it.
Gel  Gel is usually a transparent, semisolid dosage form. According to the FDA’s definition, “… a gel is a semisolid dosage form that contains a gelling agent to provide stiffness to a solution or a colloidal dispersion.”

Gelling agents are synonymous with thickeners, which increase viscosity and provide a complex internal structure (to find examples for thickeners, refer to Section 2 of this chapter). Gels may also contain fragrance beads and exfoliating beads, as some skin cleansing gels do. Additional examples for gels include hair styling gels, facial cleansing gels, shaving gels, after-shave gels, after-sun gels, extrudable deodorant and/or antiperspirant gels, and hand sanitizer gels, among others.

Based on the nature of the vehicle, two main types of gels are distinguished, including the following:

- **Water-based** formulations, such as facial cleansers; and
- **Hydroalcoholic** formulations, such as hair styling gels and hand sanitizers.

Gels contain a higher amount of water compared to other semisolid dosage forms. As water evaporates after application, it provides a cooling effect. This can be advantageous in the case of sunburn products when the cooling sensation can also be perceived as an analgesic (i.e., pain reliever) effect, and also in the case of after-shave gels where water and/or alcohol evaporation has a refreshing effect.

The formulation of gels usually starts with hydration of the thickener, which may take hours. As discussed in Section 2 of this chapter, certain thickeners are not stable at extreme pH values, and they may be sensitive to shearing. These characteristics should be taken into account when selecting the thickener. After the thickener is completely hydrated, the additional ingredients can be added and mixed until uniform. Smelly and colored ingredients are usually added at the end, similar to solutions.

**DID YOU KNOW?**

Today, toothpaste gels are also available on the market. They can be considered a combination of a toothpaste and a gel. Their purpose of use is identical to that of toothpastes, i.e., cleaning and polishing the teeth and stain removal.

Stick  A stick is a solid dosage form that is made of waxes and a smaller amount of oils. According to the FDA’s definition, “… a stick is a dosage form prepared in a relatively long and slender often cylindrical form.”

Examples for sticks include color cosmetics, such as lipsticks, lip liners, eyeshadow sticks, eyeliners, blush pencils, and concealers, as well as personal care products, such as deodorant/antiperspirant sticks and sunscreen sticks. Sticks are advantageous when consumers do not want to touch and apply products with their fingers.
They deliver the colors or active ingredients, such as antiperspirant or sunscreen ingredients, by a rubbing action.

Sticks are made by a specific technique called molding. First, the waxy ingredients that are solid at room temperature are melted and mixed with the oils and additional ingredients. While still hot, the mix is poured either into the final containers, such as lip balm cases, or into metal or plastic molds and allowed to cool. As the sticks cool, they take the shape of the mold/package. For lipsticks, a final step, called flaming, is usually also included to provide the sticks with a shiny surface (see more detail on the molding technique in Section 1 of Chapter 4).

**Aerosol** Aerosols are more of a packaging choice than a specific product type. Many of the above-discussed dosage forms can be produced in the form of an aerosol, including lotions, creams, and suspensions, if a proper can, propellant, and nozzle setup is used. They are composed of a product concentrate and a liquefied or compressed gas propellant. According to the FDA’s definition, “... an aerosol is a product that is packaged under pressure and contains various ingredients that are released upon activation of an appropriate valve system.”

Aerosols are easy to use and provide a quick drying effect, which makes them popular for certain applications. Examples for aerosol products include hair sprays, hair mousse, shaving cream, deodorants/antiperspirants, sunscreens, and sunless tanners.

The product concentrate is made as if it were a regular product, such as a cream. Then, the concentrate and the propellant are filled into a can, usually using the pressure filling technique. During this technique, first the product concentrate is filled into the can and the valve is crimped in place. Then, the propellant is filled into the can under pressure through the valve. This procedure requires special caution; therefore, aerosols are usually packaged in specialized buildings by specialized personnel.

Aerosol cans are made up of four components: the container, the valve, the actuator, and the cap. The type of actuator and product concentrate has to be selected according to the required application. For shaving foam, an actuator with a larger nozzle and a good foaming emulsion are optimal. These together can provide a product that is able to stand on the palms/face. On the other hand, for an aerosol sunscreen, an actuator with a small nozzle and a light, easily dispersible, and quickly evaporating product is recommended.

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**DID YOU KNOW?**

Foams can be generated from aerosol cans and non-aerosol containers as well. In the case of foams generated from aerosol cans, the product concentrate is an emulsion, which is filled into the can with propellants. An example for this type of foam is shaving foam.
GLOSSARY OF TERMS FOR SECTION 3

Aerosol: A product that is packaged under pressure and contains various ingredients that are released upon activation of an appropriate valve system.

Anhydrous: Waterless, water free.

Aqueous: Water-based.

Capsule: A solid dosage form consisting of a shell and a powder or liquid filling.

Cream: A semisolid emulsion with medium viscosity. It is more viscous than a lotion, but less viscous than an ointment.

Dosage form: The final physical form of a mixture of ingredients that consumers can take in their hands, purchase, and use.

Emulsion: Usually a white, opaque system that consists of at least two immiscible liquids, one of which is dispersed as droplets (internal phase) in the other (external phase). The system is generally stabilized with emulsifiers.

Gel: A clear semisolid dosage form that contains a gelling agent, which provides stiffness to the product.

Hydroalcoholic: Containing a mixture of water and alcohol.

Liquid dosage form: A dosage form that has a liquid consistency and is freely flowing. It cannot be directly taken into the hands since it would flow off the hand.

Loose powder: A solid dosage form containing a freely flowing mixture of different dry solid ingredients.

Lotion: A low-viscosity liquid emulsion.

Ointment: A highly viscous, usually greasy, semisolid dosage form. It is more viscous than a cream.

Paste: A very thick semisolid dosage form containing a high amount of solids finely dispersed in the vehicle.

Pressed powder: A solid dosage form that contains a freely flowing mixture of different dry solid ingredients in a compressed form.

Sedimentation: A process during which suspended particles in a suspension slowly settle down at the bottom of the container.

Semisolid dosage form: A dosage form that is highly viscous; it is thinner than solids but thicker than liquids.

Solid dosage form: A dosage form that consists of primarily dry solid particles mixed and/or pressed together, or waxy ingredients molded into a specific shape.

Solution: A clear, homogeneous liquid dosage form that contains one or more chemical substances dissolved in a solvent or mixture of mutually miscible solvents.

Stick: A solid dosage form that is made of waxes and a smaller amount of oils and is prepared in a relatively long cylindrical form.
Stokes’ law: A mathematical equation that describes the separation of emulsions and sedimentation of suspensions.

Suspension: An opaque liquid dosage form that contains solid particles dispersed in a liquid vehicle.

REVIEW QUESTIONS FOR SECTION 3

Multiple Choice Questions

1. Which of the following dosage forms is made of a gelatin shell?
   a) Paste
   b) Gel
   c) Capsule
   d) Lotion

2. Which of the following is a liquid dosage form?
   a) Solution
   b) Paste
   c) Gel
   d) Powder

3. What is the internal phase in an oil-in-water (O/W) emulsion?
   a) Oil
   b) Water
   c) Both
   d) None of them

4. Which of the following contains the highest amount of water typically?
   a) Oil-in-water emulsion
   b) Water-in-oil emulsion
   c) Ointment
   d) Gel

5. Which of the following dosage forms typically contain thickeners?
   a) Gels and suspensions
   b) Solutions and gels
   c) Ointments and gels
   d) Sticks and gels
6. What is the major difference between a solution and a suspension?
   a) The type of the propellant
   b) The type of the vehicle
   c) The solubility of solid ingredients dispersed in the liquid vehicle
   d) All of the above

7. What is the major difference between a cream and a lotion?
   a) Color
   b) Viscosity
   c) pH
   d) The type of the vehicle

8. Which of the following increases an emulsion’s instability according to Stokes’ law?
   a) Viscosity of the continuous phase
   b) Internal phase’s droplet size
   c) Difference in the phases’ densities
   d) All of the above

9. The term “dosage form” can be defined as ___.
   a) The physical form of the ingredients (cosmetic ingredients and/or active ingredients)
   b) The amount of the cosmetic ingredients and/or active ingredients used in a product
   c) The final physical form of a mixture of ingredients (cosmetic ingredients and/or active ingredients)
   d) The amount of a product that is recommended to be used daily

10. When mixing oils with water in the presence of an emulsifier, what does the type of the forming emulsion depend on?
    a) The amount of the water phase
    b) The amount of the oil phase
    c) The solubility of the emulsifier, if it is water-soluble, O/W emulsion forms
    d) The solubility of the emulsifier, if it is water-soluble, W/O emulsion forms

Fact or Fiction?

_____ a) Both lotions and creams are emulsions.
_____ b) All foams are aerosols.
_____ c) Suspensions are thermodynamically unstable formulations.
_____ d) Creams are more viscous than lotions.
Matching

Match the dosage forms in column A with their appropriate definition in column B.

<table>
<thead>
<tr>
<th>Column A</th>
<th>Column B</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Aerosol foam</td>
<td>A. A long, slender solid dosage form based on waxes and oils</td>
</tr>
<tr>
<td>2. Capsule</td>
<td>B. Clear, homogeneous liquid dosage form</td>
</tr>
<tr>
<td>3. Cream</td>
<td>C. Compressed solid dosage form made of a blend of powders</td>
</tr>
<tr>
<td>4. Gel</td>
<td>D. Emulsion containing a propellant</td>
</tr>
<tr>
<td>5. Loose powder</td>
<td>E. Liquid dosage form containing insoluble solid particles</td>
</tr>
<tr>
<td>6. Lotion</td>
<td>F. Opaque, thick semisolid dosage form</td>
</tr>
<tr>
<td>7. Ointment</td>
<td>G. Opaque, thin liquid dosage form</td>
</tr>
<tr>
<td>8. Paste</td>
<td>H. Solid dosage form consisting of a shell and a filling</td>
</tr>
<tr>
<td>9. Pressed powder</td>
<td>I. Solid dosage form, a mixture of freely flowing powders</td>
</tr>
<tr>
<td>10. Solution</td>
<td>J. Usually transparent, viscous semisolid dosage form</td>
</tr>
<tr>
<td>11. Stick</td>
<td>K. Very thick semisolid dosage form with a high amount of solids</td>
</tr>
<tr>
<td>12. Suspension</td>
<td>L. Yellowish, opaque, greasy, and sticky semisolid dosage form</td>
</tr>
</tbody>
</table>

Matching

Match the examples in column A with their appropriate dosage form in column B.

<table>
<thead>
<tr>
<th>Column A</th>
<th>Column B</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Aftershave balm</td>
<td>A. Aerosol</td>
</tr>
<tr>
<td>2. Baby powder</td>
<td>B. Capsule</td>
</tr>
<tr>
<td>3. Bath bead</td>
<td>C. Cream</td>
</tr>
<tr>
<td>4. Compact blush</td>
<td>D. Gel</td>
</tr>
<tr>
<td>5. Hair pomade</td>
<td>E. Loose powder</td>
</tr>
<tr>
<td>6. Hair spray</td>
<td>F. Lotion</td>
</tr>
<tr>
<td>7. Hand sanitizer gel</td>
<td>G. Ointment</td>
</tr>
<tr>
<td>8. Leave-in hair conditioner</td>
<td>H. Pressed powder</td>
</tr>
<tr>
<td>9. Lip balm</td>
<td>I. Solution</td>
</tr>
<tr>
<td>10. Mouthwash</td>
<td>J. Stick</td>
</tr>
<tr>
<td>11. Nail polish</td>
<td>K. Suspension</td>
</tr>
</tbody>
</table>
REFERENCES
