Section II

Hygiene Products

Part 1: Cleansers

Chapter 10: Bar cleansers

Anthony W. Johnson and K.P. Ananthapadmanabhan
Unilever HPC R&D, Trumbull, CT, USA

BASIC CONCEPTS

- There are two basic types of cleansing bar – soap bars and synthetic detergent bars.
- Like all surfactant-based products, cleansing bars can be harsh or mild to skin.
- Mild cleansing bars have a key role in fundamental skin care.
- Mild cleansing bars have positive benefits for patients with skin diseases.

Introduction

Cleansing bars – historical perspective

Anecdotally, soap was discovered by prehistoric man, noticing a waxy reside in the ashes of an evening camp fire around a burnt piece of animal carcass. The waxy material was soap. Potash from the ashes (KOH) had hydrolyzed triglyceride from animal fat to produce potassium soap and glycerol. Actual historical records show soap-like materials in use by Sumerians in 2500 BC and there are references to soap in Greek and Roman records and by the Celts in northern Europe. As European civilizations emerged from the Dark Ages in the 9th and 10th centuries soap making was well established and centered in Marseilles (France), Savona (Italy), and Castilla (Spain). In those days soap was a luxury affordable only by the very rich. Mass manufacture of soap started in the 19th century and was well established by the turn of the century with individually wrapped and branded bars.

Synthetic detergents emerged in the 20th century, primarily for fabric washing products. While there are many types of synthetic detergent, very few are suitable for making cleansing bars. It is difficult to make a solid product that is able to retain a solid form during multiple encounters with water and at the same time able to resist cracking, crumbling, and hardening when drying between uses. Soap is ideal for making bars but that is not to say that some of the early soap bars did not dry out and develop cracks or become soft and mushy in humid environments. Modern manufacturers are able to formulate soap bars to control the physical behavior in use and when drying between uses. Soap-based bars continue to dominate the cleansing bar market around the world, but synthetic detergent bars are gaining an increasing share of market (30% of bars sold in the USA).

The wide range of soap bars available in the skin marketplace today might suggest a wide range of functionality but this is not the case. To develop new claims and gain shelf space in big supermarkets, manufacturers create variants by minor modifications of their basic bar types – the functional properties of soap bar variants are usually very similar – they all lather and they all clean.

Formulation technology of cleansing bars

Cleansing bars are made of surfactants that are solid at room temperature and readily soluble in water. While there are scores of commercially available surfactants only two, alkyl carboxylate (soap) and acyl isethionate (syndet), are used on a large scale for manufacture of cleansing bars (Figure 10.1).

These two surfactant types are quite different, leading to different sensory experiences for the consumer and also differences in their interactions with skin. Soap and syndet have in common that they have the physical properties required to be processed into bars that can withstand the challenges of use in the home. As bars they must have a consistent performance – they must lather easily when new but just as readily as the bar is used up over a period of weeks or months. They should produce lather quickly and easily and should not feel gritty in use. The rate of wear should be optimum, neither too fast nor too slow. They must

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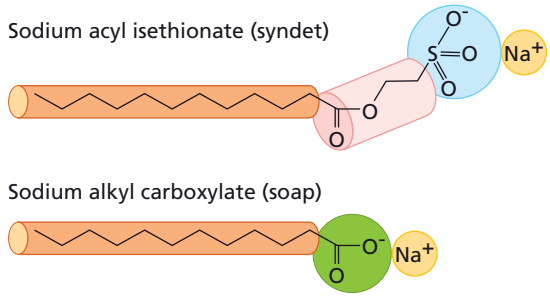


Figure 10.1 Schematic representation of the molecular structures of soap (sodium alkyl carboxylate) and syndet (sodium acyl isethionate) showing the difference in head group structure and size.

dry quickly after use but must not crack; they should not break apart if dropped, and should not absorb water and become mushy in a humid environment, like a bathroom. There are not many surfactants that can satisfy this list of seemingly simple practical requirements.

Broadly speaking, there are two types of manufacturing process for making cleansing bars: (a) a continuous process of milling, extrusion, and stamping; and (b) a batch process of melt casting.

Continuous processing

The continuous process starts with synthesis of the basic surfactant, alkyl carboxylate, and then processing this as a solid through various steps during which other ingredients are added until the final composition is attained. After milling and mixing steps to ensure homogeneity, the compounded soap it is extruded as a continuous bar which is chopped and stamped into the individual bar shape of the final product. The technical demands of the continuous process impose constraints on composition and ingredient addition – but it is the fastest and cheapest way to make a cleansing bar.

Batch processing

The essence of the melt cast approach is to make the surfactant and add any desired ingredients to form a hot liquid melt which is poured into individual bar size casts and allowed to set as it cools. This is a much more expensive process but allows for a wider range of additional ingredients in the product formulation. The continuous process is used for most of the mass market bars and the melt cast process for specialist bars often sold in boutiques, custom outlets, and department stores.

Soap bars

There are several major compositional types of soap bar with distinct bar properties and in use behaviors – speed and type of lather, rate of use up, aroma, skin compatibility, tendency for mush, etc. Most bars are either basic or superfatted soap. Basic soaps are blends of medium chain length fatty acid sodium salts (Figure 10.1). Superfatted soaps are similar but with additional fatty acid. There are other categories of soap bars based on the use of specialist ingredients: transparent bars, antibacterial bars, and deodorant bars. There are large numbers of specialist bars that are simply soap containing a wide range of colors, fragrances, and emotive ingredients such as vitamins, aloe, chamomile, and other natural extracts. The emotive ingredients in specialist bars are there to appeal to the senses and emotions with no real expectation that they have any detectable benefit for the skin.

Basic soap

Soap is the sodium salt of a fatty acid. As the salts of weak acids, soaps form alkaline solutions as they dissociate in water. The pH of soap is typically in the pH range 9–11. This is not sufficient to be overtly irritating to skin but is sufficiently high to negatively impact the pH-dependent processes of the stratum corneum which has a natural pH of around 5.5. The fatty acids used in soap making are natural, derived from animal or plant sources, with the most common chain lengths in the range C12 (e.g. coconut fatty acid) to C18 (e.g. tallow/rendered animal fat). C12–14 soaps are soluble and lather easily. C16–18 soaps are less soluble but good for forming solid bars. The plant oils used in soap making are mostly triglycerides and when treated with lye and/or caustic soda they hydrolyze to the fatty acid sodium salts (soap) and glycerol.

Superfatted soap bars

Simple soaps are good cleansers but also drying to skin. Less drying soaps are made by adjusting the soap making process to leave an excess of free fatty acid in the final soap composition (superfatted soaps). This excess fatty acid reduces the lipid stripping and drying effects of a soap bar to a small extent. Beauty soaps are typically superfatted soaps.

Transparent soaps

There are several types of transparent or semi-transparent soap bars. The earliest was a rosin glycerin soap bar developed by Andrew Pears in 1789. The ingredients of Pears patented transparent soap were sodium palmitate, natural rosin, glycerine, water, C12 soap, rosemary extract, thyme extract, and fragrance. The Pears soap of today is made by essentially the same process, which involves dissolving the raw soap and other ingredients in alcohol, pouring into moulds followed by up to 3 months of evaporation and drying.

A different type of transparent bar was introduced in 1955 by Neutrogena based on a patented formulation invented by a Belgian cosmetic chemist, Edmond Fromont. His novel formulation was based on triethanolamine soap (in other words, soap where the neutralizing cation is triethanolamine

instead of the usual sodium). The ingredients of the Neutrogena bar are triethanolamine stearate, C12–18 soaps, glycerine, water, and a range of minor ingredients including a little lanolin derivative and fragrance. Triethanolamine forms acid soaps so the pH of the Neutrogena bar at pH 8–9 is lower than a regular soap with sodium as the cation.

Antibacterial and deodorant soap bars

Medicated or antibacterial soaps are a large subcategory of the bar soap market. These products are basic soaps containing one of a limited number of approved antibacterial agents. Some of these products are positioned as deodorant soap to inhibit the odor-producing bacteria of the axilla. Washing with any soap is effective for removing and killing the bacteria on skin and the value and contribution of added antibacterial agents is controversial. However, there are a variety of tests developed to assess the effectiveness of antibacterial soaps and there is no doubt that there is some deposition of the antibacterial agents on skin during washing and this is expected to reduce the effectiveness of any residual bacteria and to reduce colonization by other microbes.

Non-soap detergent bars – syndet bars

Because soap is cheap and easy to manufacture the cleansing bar market has remained predominantly soap bars. However, there has been one non-soap bar technology that has achieved a significant place in the US market over the last 50 years and is now extending its reach to other regions of the world. This product, introduced to the US market in 1957 as the Dove bar, is based on patented acyl isethionate as the surfactant component in combination with stearic acid which has a dual function of providing the physical characteristics for forming a stable bar and also acting as a significant skin protecting and moisturizing ingredient. The high level of stearic acid in the Dove bar is the basis of the one-quarter moisturizing cream in the product. When the patents for this novel technology ran out, several other acyl isethionate bars were introduced in the USA market including Caress, Olay, Cetaphil, and Aveeno.

Market overview

There are hundreds of cleansing bars on the market but relatively few that are widely sold. Most of the cleansing bar market is supplied by a small number of manufacturers and a limited number of brands. Figure 10.2 shows the segmentation of the US market for soap and syndet cleansing bars.

Preservatives

It is of interest that soap bars and syndet bars are self-preserved in the sense that they provide a hostile environment for microorganisms and do not need to contain a preservative to maintain product quality.

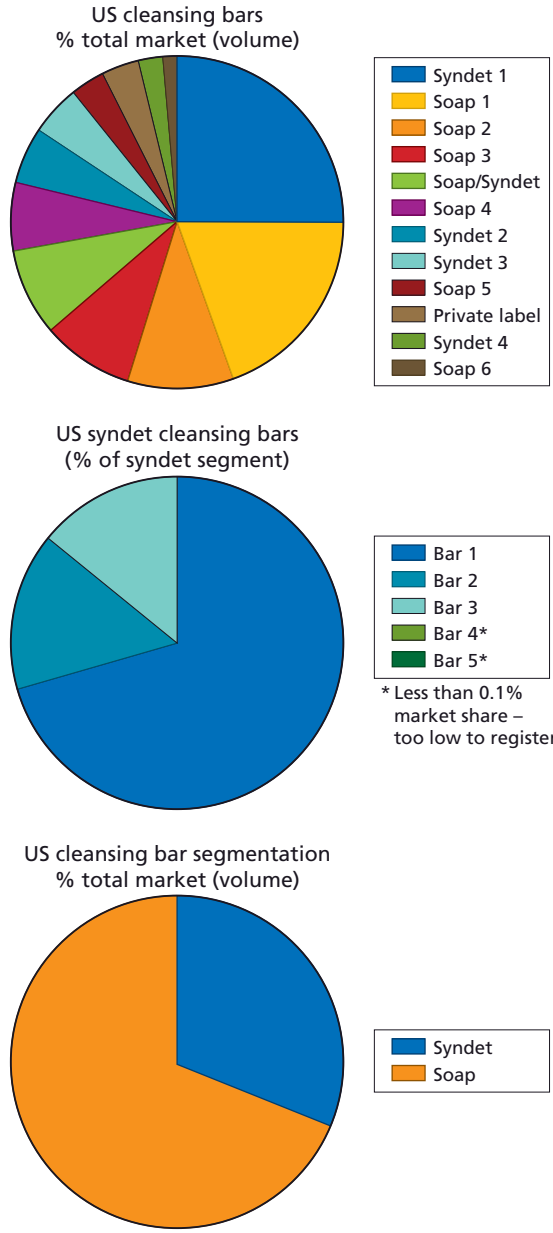


Figure 10.2 Segmentation of cleansing bar market (based on average data for 2006, 2007, and 2008). The charts show shares (volume) for leading soaps and syndet bars. Brands not identified. Brands and their market shares vary somewhat year to year and may vary considerably over time.

Impact of cleansing bars on skin structure and function

Washing with soap removes dirt and grime from skin and is very effective for removing germs and preventing the spread of infection. There is an appreciation that some soaps are harsh and others mild, but washing with soap is so routine and commonplace that most people give no thought to the cleansing process or its impact on skin. This is a mistake.

Research over the last few years has revealed several mechanisms by which soap interacts with skin structures to adversely affect normal functioning. It is now clear that mild cleansing has significant benefits for both diseased and healthy skin. Mild cleansing can reduce the symptoms of common skin conditions such as eczema, acne, and rosacea and can enhance the attractiveness of normal skin.

Surfactant interaction with the skin–stratum corneum

As described in other chapters of this book, the outer layer of skin, the stratum corneum, is a very effective barrier to the penetration of microorganisms and chemicals unless compromised by damage, disease, or a intrinsic weakness caused by one of the genetic variations now known to impact the functioning of the stratum corneum. Whatever the normal state of the stratum corneum for an individual, the most challenging (i.e. potentially damaging) environmental factor, apart from industrial exposure to solvents and other harsh chemicals, is cleansing. And yet cleansing is a key element of good everyday skincare and there is much variation in the damaging potential of different cleansing products including cleansing bars. Understanding how cleansing products impact skin and knowing the mildest cleansing product technologies is a basic requirement for achieving fundamental skin care.

Soap bar interactions with the stratum corneum

The properties of soap that make it an effective cleanser also determine that it can be drying and irritating to skin. The high charge density of the carboxyl head group of the soap molecule promotes strong protein binding which is good for cleansing but bad for skin. Soap binds strongly to stratum corneum proteins and disturbs the water-holding mechanisms of the corneocytes. Soaps also denature stratum corneum enzymes essential for corneocytes maturation and desquamation. The result is an accumulation of corneocytes at the skin surface and the characteristic scaly, flaky, roughness associated with dry skin.

In addition to damaging proteins, soap and other cleansers can disrupt and strip out the lipid bi-layers of the stratum corneum. The bipolar structure of the soap molecule is similar to the bipolar structure of the three major lipid types that make up the lipid bi-layers of the stratum corneum (fatty acids, cholesterol, and ceramides). Soap disrupts the bi-layer structure of these lipids in the stratum corneum and thereby reduces the effectiveness of the stratum corneum water barrier. Transepidermal water loss (TEWL) is increased through the leaky barrier. Also, disruption of the structured lipid matrix around stratum corneum cells (corneocytes) allows the highly soluble components of the skin's natural moisturizing factor (NMF), contained in the protein matrix of the corneocytes, to leach out. Leaching is increased by further cleansing or even simply by contact with water. This process explains the paradox that water is often a major factor for causing dry skin. Effects on the key lipid structures of the stratum corneum add to the damage caused by soap–protein interactions and exacerbate the development of skin dryness – remembering that dry skin is not simply a lack of moisture but a disturbance of normal stratum corneum function with retention and accumulation of superficial corneocytes. The build up of corneocytes at the skin surface is responsible for many symptoms associated with "dry" skin – scaling, flaking, roughness, dull appearance (due to light scattering), tightness, loss of resilience/flexibility/elasticity, and ultimately cracking and irritation.

All soaps have the ability to induce dry and irritated skin and these effects are most evident in challenging environmental condition – cold or hot temperatures with low humidity, excessive exposure to solar UV radiation, and prolonged exposure to wind. The drying potential of soap varies according to composition such as the balance between soluble (C12–14) and less soluble chain lengths (C16–18) of the fatty acids most commonly used to make soap – the higher the soluble component the more drying the soap. Superfatted soaps are a little milder than simple soaps, and triethanolamine soap and glycerol bars the mildest of the commonly available soap bars.

Synthetic detergent bar interactions with the stratum corneum

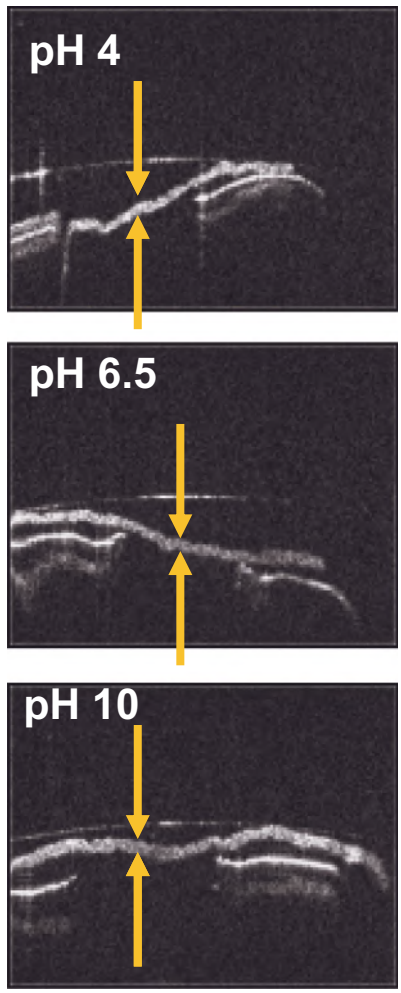
Synthetic detergent bars (syndet bars) have been available on the US market for 50 years and represent a clear technologic difference from soap-based cleansing bars. Nearly all common synthetic detergent bars are based on an anionic surfactant, acyl isethionate. At the time of writing (2008) these bars account for 40% of the cleansing bars sold in the USA. Alkyl glycerol ether sulfonate (AGES) and monoalkyl phosphate (MAPS) are two of a small number of other synthetic detergents that have been tried for manufacture of cleansing bars but none of these have been successful in the US market.

Ironically, because syndet bars are shaped like soap bars and used for cleansing just like a soap bar, most people believe that synthetic detergent bars are just another variety of soap. Most consumers are unaware that there is a fundamental compositional difference between soap and syndet bars that impacts their interactions with skin such that syndet bars are milder than soap bars during cleansing. There is a greater difference between soap and syndet cleansing in terms of healthy and attractive skin than most people realize. It is important for healthcare professionals and dermatologists to appreciate the difference between soap and syndet bars because studies show the difference in mildness is very relevant for their patient groups (see studies described below).

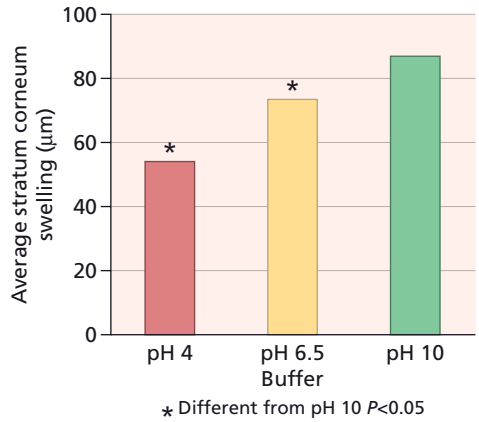
Soap (alkyl carboxylate) and syndet (acyl isethionate) are both anionic surfactants and like all anionic surfactants they interact with skin proteins and skin lipids. But because of the difference in head group physical chemistry soap interactions are more intense leading to a higher potential for inducing dryness and irritation. The carboxylate head group is compact, leading to a high charge density that facilitates binding and denaturation of proteins. By contrast, the isethionate head group is large and diffuse, producing a low charge density and less ability to interact with proteins (Figure 10.1)

A second and most important factor contributing to the mildness of the isethionate syndet bar is the ability to formulate acyl isethionate with high levels of stearic acid without losing the ability to lather. In fact, the lather is more dense and creamy than the lather of a typical soap bar. The stearic acid component of the isethionate syndet bar acts as a moisturizing cream and deposits on skin during cleansing, adding to the relative mildness of these types of bar. Superfatting is, in principle, a similar way to reduce the harshness of plain soap but the results are much more modest because the initial harshness of soap is higher than syndet and the upper limit of practical superfatting is closer to 10% compared to the 20–25% fatty acid that can be formulated in an isethionate bar.

Another difference between soap and syndet bars is pH. Soap has an alkaline pH typically around pH 10–11 whereas isethionate/stearic acid bars are close to pH neutral with a pH of a little over 7. The pH of glycerol bars is in the range pH 8–9. These differences in pH have an effect on the interaction of cleansing bars with the stratum corneum. Skin proteins swell markedly if the cleanser pH is highly alkaline (pH >8). Optical coherence tomography (OCT) pictures of stratum corneum after exposure to acidic, neutral, and alkaline pH conditions and the corresponding swelling show that there is significantly higher swelling in alkaline pH solutions (Figure 10.3). Strongly binding detergent molecules can increase the swelling further.



(a)



(b)

Figure 10.3 Swelling of the stratum corneum in different pH buffer solutions. (a) Optical coherence tomography (OCT) images of *ex vivo* skin treated with different buffer solutions. The arrows show the position and thickness of the stratum corneum. (b) The bar chart provides a graphic representation of the same difference.

High pH also has an impact on stratum corneum lipids. An alkaline pH can ionize fatty acids in the lipid bi-layers making them more like "soap" molecules and destabilizing the highly organized structure of the bi-layers.

These factors contribute to the differences in mildness of soap and syndet bars. Environmental scanning electron microscopy pictures of the skin surface and the corresponding transmission electron microscopy images of the protein-lipid ultrastructure of human skin washed under exaggerated conditions (nine repeat washes) with a syndet and a soap bar are seen in Figure 10.4. It is evident from the micrographs that the syndet bar washed sample exhibits well-preserved cells with intact proteins and lipids compared with the soap washed sample.

Studies comparing mildness properties of soap and syndet cleansing bars

Many consumers are not aware of the differences in drying and irritation potential between soap bars and synthetic detergent bars. In practice, most cleansing products are not drying to an extent that is readily perceivable and under normal conditions of use cleansing bars seldom produce irritation and inflammation. However, in other circumstances, particularly drying environmental conditions or with compromised diseased skin, some cleansing bars can cause severe dryness and irritation. Why is this?

Under normal conditions it is likely that the skin is superficially and temporarily dried by most cleansers but is rapidly able to restore its ability to hold moisture and maintain healthy functioning. However, under challenging environmental conditions, particularly the harsh cold winters of Canada and the northern USA and the hot dry summers of the central plains and western desert areas of the USA, recovery after washing is likely less rapid. Without supplemental moisturization from the cleansing product or a skin cream or lotion applied after washing, a vicious cycle of damage and inadequate recovery is quickly established, leading initially to dry skin but quickly progressing to deeper damage with fissuring of the stratum corneum (cracking), deeper penetration of the surfactant, frank irritation, and ultimately full-thickness cracking of the stratum corneum leading to chapping and bleeding. This may sound extreme but anyone with a tendency to develop dry skin will recognize this scenario of raid deterioration to more severe irritation when the weather is drying – particularly for handwashing.

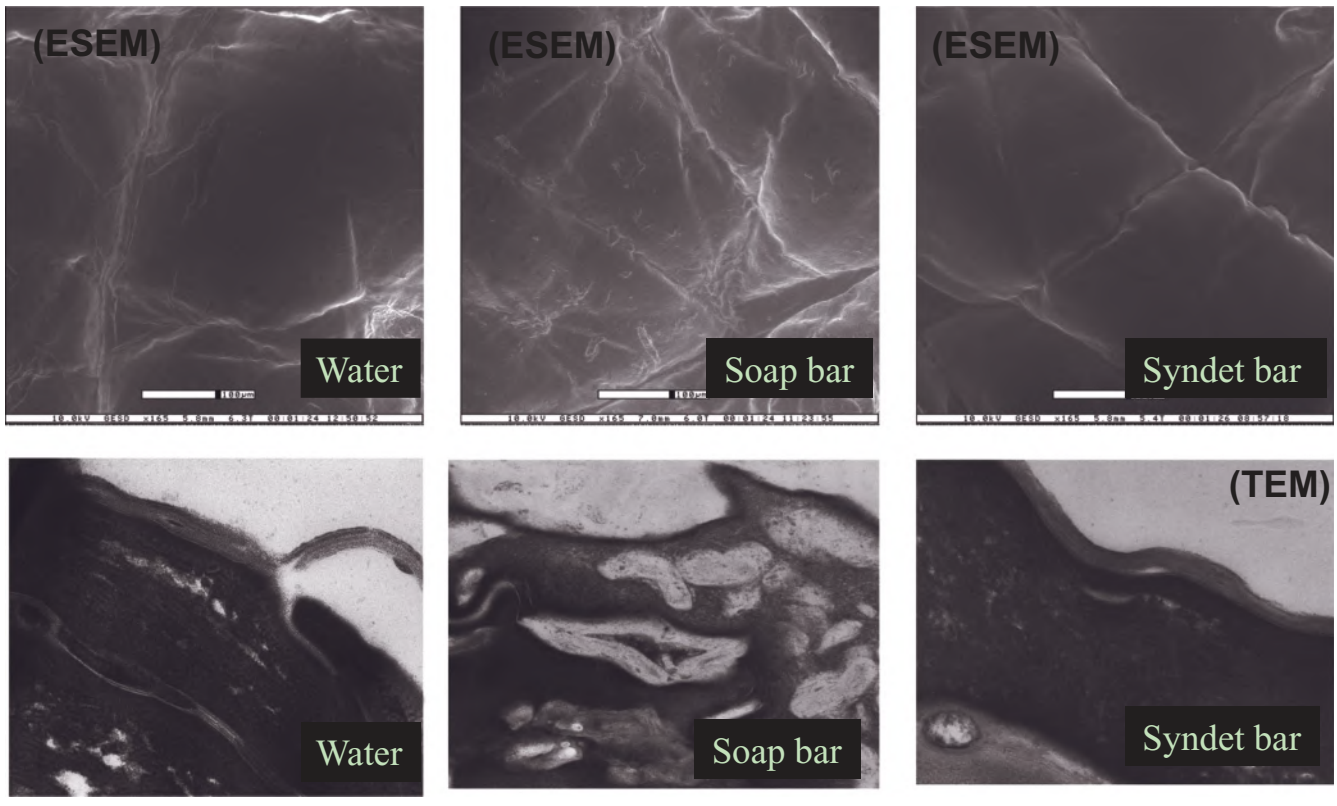


Figure 10.4 Environmental scanning electron micrographs (ESEM) and transmission electron micrographs (TEM) images of human skin washed with water, soap, and a syndet bar (9 repeat washes). Water washed and mild syndet bar washed skin shows well-preserved lipids and plumped (hydrated) corneocytes. By contrast, images of harsh soap-washed skin show significant removal of lipids and damage to proteins.

The first practical demonstration that syndet bars are fundamentally less damaging to skin than soap bars was a study published by Frosh and Kligman [1]. Using a new and simple method, the soap chamber test, they examined the skin irritation potential of all the cleansing bars they could purchase locally in Philadelphia at that time. One bar stood out as exceptionally mild compared with the rest of the marketplace (17 other bars tested) and this was a patented alkyl isethionate bar called Dove. Now that the Dove patent has expired a number of manufacturers sell similar isethionate syndet bars.

The difference in relative mildness of soap and isethionate/stearic acid syndet bars is easily demonstrated in the standard wash and rinse tests used by manufacturers of cleansing products. The forearm controlled application test (FCAT) and leg controlled application test (LCAT) are 5-day repeat washing tests. Skin condition is evaluated daily by a variety of techniques including visual dryness, superficial and deeper hydration measured instrumentally, TEWL to assess barrier performance, and erythema to assess irritation. Typical results obtained by comparing soap and syndet cleansers in a FCAT test are shown in Figure 10.5.

An increase in stratum corneum dryness has a negative effect on the mechanical properties of the corneum. Changes in stratum corneum elasticity/stiffness measured in a standard clinical test after washing with soap and syndet bars are shown Figure 10.6. While soap washing increases skin stiffness markedly, the milder syndet bar maintains the original skin condition. Such effects are magnified further under low humidity and winter conditions and can lead to microcracks in the stratum corneum and increased water loss, plus increased vulnerability to penetration of external chemicals into skin.

Concern is sometimes expressed that industry standard tests are exaggerated and do not reflect real consumer experience. The evidence accumulated by manufacturers and published in peer-reviewed journals demonstrates that effects in standard tests are indeed predictive of what can be

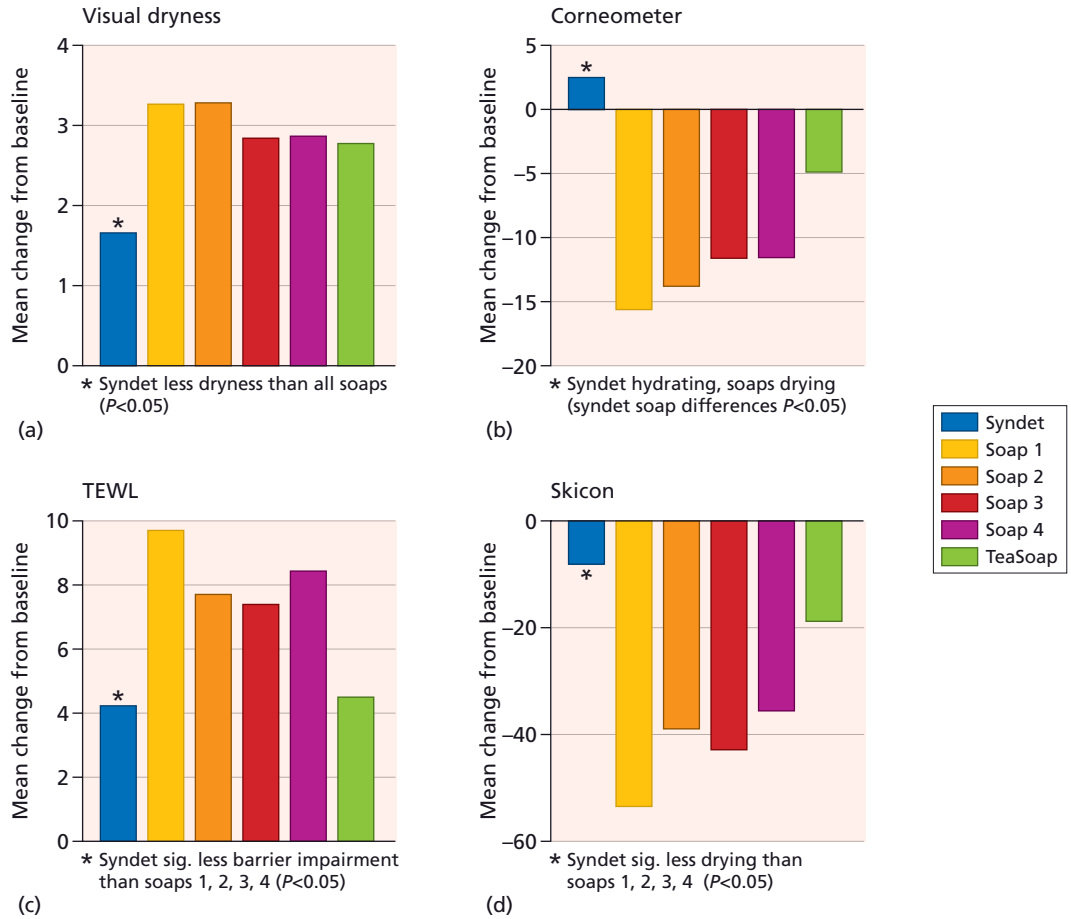


Figure 10.5 Skin changes after 5 days of twice daily washing with soaps and syndet using the forearm controlled application test (FCAT) method. (a) Visual dryness; (b) transepidermal water loss (TEWL) – skin moisture barrier; (c) Corneometer – stratum corneum hydration; (d) Skicon – superficial stratum corneum hydration.

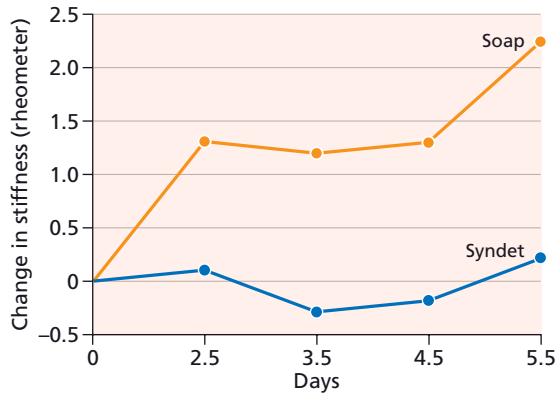


Figure 10.6 Changes in skin mechanical properties (stiffness) after 5 days of twice daily washing with soap and syndet using the FCAT method. Soap washing induced a progressive increase in stratum corneum stiffness as measured using a linear skin rheometer whereas the syndet bar did not induce stiffness.

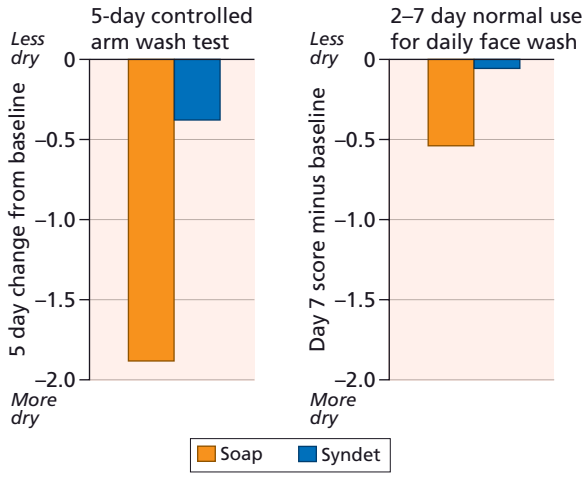


Figure 10.7 Skin dryness induced by soap and syndet bars in a 5-day controlled arm wash test compared to dryness induced by 2–7 days of normal use once daily for facial cleansing. Arm wash test carried out on the same subjects as the 7-day facial wash test. Most soap users were unable to continue soap use for a full week. Most syndet users were able to complete a full week of daily face washing – dryness scores are based on assessments made on day 7 for the whole panel.

experienced in normal use under realistic but challenging environmental conditions. Figure 10.7 shows results of a study where women used soap or syndet for face washing for a week during the Canadian winter. They were not allowed to use a facial moisturizer during the study. Under the cold drying conditions of this study the soap users rapidly experienced intense drying and soreness whereas the syndet users were mostly able to tolerate the withdrawal of their normal after-wash moisturizer for a week.

Practical implications of mild cleansing for patients with common skin disease

The studies described in this section [2,3] were based on a simple hypothesis that switching patients with common skin diseases from their current soap bar cleanser to a milder syndet bar cleanser would minimize symptoms and generally help in managing their skin condition. The patient groups studied were atopic dermatitis, acne, and rosacea. The results show that patient symptoms were reduced and general skin quality improved.

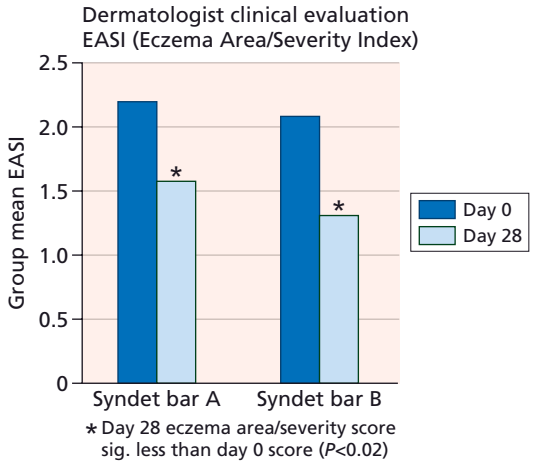
Benefits of mild cleansing for adults and children with mild atopic dermatitis

A total of 50 patients with mild atopic dermatitis were enrolled for a 4-week double-blind study carried out under the supervision of a certified dermatologist. One group of 25 patients (19 adults and 6 children <15 years) used a marketed syndet cleansing bar instead of their normal cleansing bar for showering during the 4 weeks of the study. A second group of 25 patients (17 adults and 8 children) used a different syndet bar based on the same acyl isethionate cleansing system. Eczema severity was measured at baseline and 4 weeks using the eczema area severity index (EASI) clinical assessment system. Other evaluations at these times were dermatologist assessment of non-lesional skin, hydration by conductance meter, and patient self-assessment by questionnaire. Results indicated good compatibility with the syndet bar as a substitute for patient's usual bar cleanser for both adults and children. In addition, it was observed that the severity of eczematous lesions reduced with both bars, general skin condition was improved, and hydration was maintained. The main results are shown in Figure 10.8.

Benefits of mild cleansing for acne and rosacea patients

In one study, a group of 50 patients with moderate acne and using topical acne medications (benzamycin or benzamycin/differin) were split into two treatment cells (25 patients per cell) and instructed to use either a syndet bar or a soap bar for 4 weeks in place of their normal cleansing bar. Patient skin condition was assessed at baseline and after 4 weeks of use. Although the clinical differences between soap and syndet in this test were not statistically significant, there was a clear trend that patients using soap experienced worsening of measures relating to skin compatibility and irritation during the 4-week period of the study and little or no change in patients using the syndet bar (Figure 10.9).

A similar protocol was used in a study of rosacea patients. Seventy patients were enrolled and divided into two subgroups for a 4-week study period. Evaluations were per-



Patient self assessment of change in skin condition from day 0 to day 28

Decreases from baseline			Increases from baseline		
Symptom	Change from day 0		Attribute	Change from day 0	
	Bar A	Bar B		Bar A	Bar B
Dryness	-1.5	-2.1	Complexion	0.2	1.3
Itching	-1.3	-2.8	Smoothness	0.7	2.7
Irritation	-1.1	-2.7	Softness	0.4	2.8
Tightness	-0.9	-1.3	Appearance	1.3	2.3
Tingling	-0.7	-1.4			
Red numbers - sig. diff from baseline at day 28 (P<0.05)					

Figure 10.8 Changes in dermatologist and patient assessment of skin condition after 4 weeks' daily use of syndet cleansing bars by adult and child (7–15 years) patients with atopic dermatitis (AD). A total of 25 patients used bar A and 25 used bar B. The patients were patients with chronic AD stabilized using a variety of treatment regimens which they continued during the trial. The bars were similar in composition with the same acyl isethionate synthetic surfactant system and different ratios of emollients.

formed at baseline and at 4 weeks. The results show a similar trend in favor of using the syndet bar (Figure 10.9).

The studies described above indicate a benefit of syndet bars for patients with disease compromised skin. Other studies have shown that use of syndet bars is helpful for skin that is compromised by treatments used to reduce the signs of photodamage such as retinoid therapy or chemical peels.

The future of cleansing bars

Bar soaps have been the most common product for skin cleansing for so long that most people never give them a second thought. However, since the late 1990s there has been a slow but steady decline in soap bar sales in favor of liquid cleansing products. This is most pronounced in the developed markets of North America and Europe. Like many market trends this change is brought about by changes in consumer needs, habits, and attitudes. Cleansing liquids have become the product of choice for the shower, liquid soaps are increasingly used for hand cleansing, and quick foaming liquids, creams, and wipes have largely replaced soap bars for facial cleansing. Nevertheless, there is little doubt that cleansing bars will remain a universal household product for many years to come.

This chapter describes the negative effects for skin associated with cleansing and provides evidence that there are real benefits for patients and consumers generally to use the mildest bar cleansers available. It has long been recognized that environmental factors facilitate the drying, irritating actions of surfactants and that people differ in their susceptibility to these effects. Only recently has it become evident that genetic variations are direct drivers of individual variations in susceptibility to develop dry and sensitive skin. It appears that loss-of-function mutations in the filaggrin gene are relatively common in humans and are the cause of mild and severe forms of ichthyosis vulgaris and atopic dermatitis. The insight that filaggrin gene mutations and variations lead to a compromised barrier that predisposes to dry skin is changing how scientists and professionals think about dry skin and healthy skin functioning. Some people have a good barrier but others are much more susceptible to environmental challenges – including cleansing.

Gene profiling is not yet a routine diagnostic procedure but susceptibility to develop dry skin is a strong indication of a compromised barrier and the need for mild cleansing to prevent surfactant-induced exacerbation of a poor barrier. The future will see new and more precise diagnostic tests enabling dermatologists and healthcare professionals to more readily identify consumers and patients who have less than optimal stratum corneum functioning. In parallel, the need to identify mild products and good cleansing practice will come into sharper focus. It will be interesting to see if the future consumer product trend is a rebalancing from soap bars to milder syndet bars or if the trend will be a more direct move from bars to liquid cleansers. Most likely the market will develop in both directions – milder bars and more use of liquid cleansers.

Conclusions

Cleansing is a basic human need and cleansing bars are the universal way to satisfy this need. Liquid products may be gaining in popularity but it will be decades before bars become redundant, if ever.

Cleansing is a challenge to skin for everyone, but for patients with skin problems the choice of cleansing product

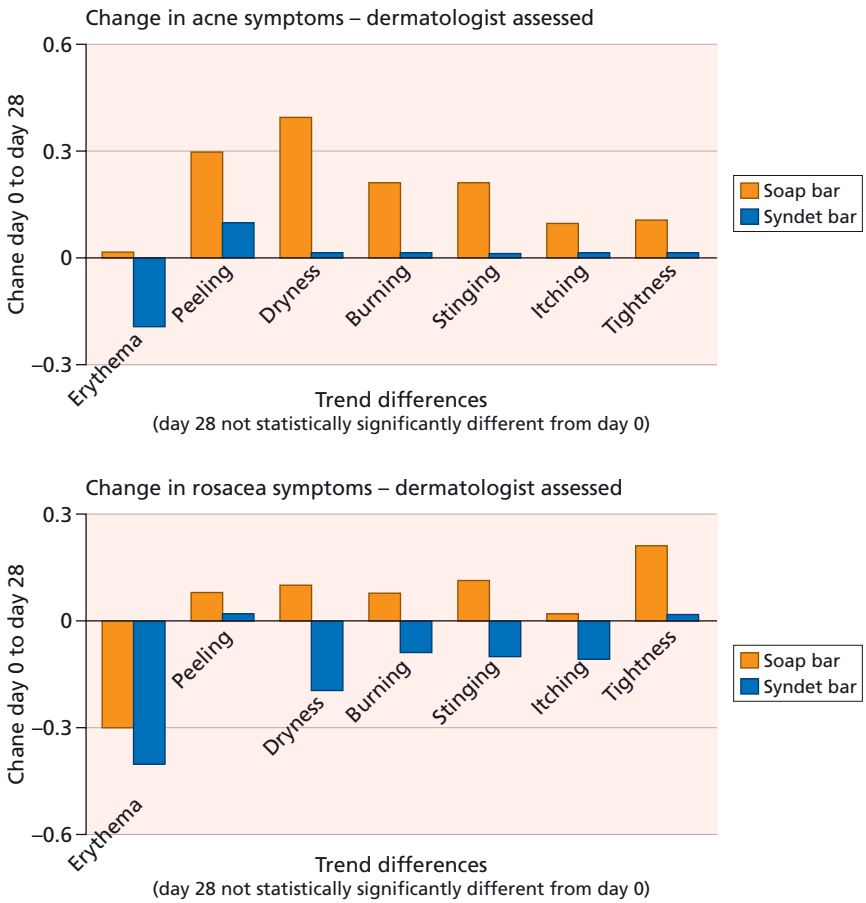


Figure 10.9 Dermatologist assessed changes in skin condition of patients with mild to moderate acne or mild to moderate rosacea after 4 weeks' use of soap or syndet bar for daily cleansing. In the acne study were 50 patients using topical benzamycin or benzamycin plus differin. In the rosacea study were 70 patients using topical metronidazole. The syndet bar was acyl isethionate synthetic surfactant and the soap bar was a standard 80/20 soap.

is the difference between exacerbation and minimization of symptoms. There is ample evidence in the literature that syndet bars are milder than soap-based bars and better for patients with common dermatologic conditions such as atopic dermatitis, eczema, acne, and rosacea. Not everyone needs to use a syndet bar but many consumers and patients currently using soap bars could experience a practical benefit by switching to syndet bar.

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Chapter 11: Personal cleansers: Body washes

Keith Ertel and Heather Focht
Procter & Gamble Co, Cincinnati, OH, USA

BASIC CONCEPTS

- Dry skin on the body is a particular issue for most consumers. Leave-on lotion application is not always viewed as a convenient intervention, so relief is sought from alternative sources such as moisturizing personal cleansing products.
- Body washes are a relatively new introduction into the armamentarium of personal cleansing products and their use is growing rapidly, particularly in developed countries.
- Body washes present unique formulation challenges and benefit opportunities compared to traditional cleansing bar forms.
- There are several distinct types of body washes. Of these, moisturizing body washes represent the greatest departure from traditional personal cleaners, having the potential to improve dry skin condition.
- Moisturizing body washes vary widely in terms of their skin effects (i.e. their ability to mitigate dryness). A product must deposit an effective amount of benefit agent on the skin during the wash–rinse process. Understanding the basis for a product's designation as "moisturizing" is key.

Background

Cleansing to remove soils from the skin's surface is a basic human need that serves both a cosmetic and a health function. While cleansing needs for the face receives considerable attention and few question the logic of specialized facial cleansers, cleansing needs for the body are often given little thought, the assumption being that any personal cleanser will suffice. This view is somewhat surprising given that body skin accounts for more than 90% of the body's total surface area and, as we will show, consumers have diverse needs and expectations from a body cleanser.

Water alone cannot effectively remove all soils from the skin and surfactant-based materials have been the cleansing aids of choice throughout recorded history. Soap was among the first cleansing aids and some of the earliest references to soap preparation are found in Sumerian and Egyptian writings, although legend holds that the article we know as soap originated by chance at Mount Sapo in Ancient Rome when fat and wood ash from sacrifices were mixed with rainwater.

Regardless of its origin, soap was the cleansing aid of choice and remained largely unchanged for centuries. The next real step-change in personal cleanser technology occurred around the time of World War I, when the first non-soap surfactant was introduced. However, bars continued as the predominant form for body cleansing and it was not until the latter part of the 20th century that liquid personal cleansing products for the body (i.e. body washes) were introduced and began to gain a foothold in some regions.

Body washes are generally less messy in use than bars (e.g. no soap mush), are more hygienic, and offer greater potential to deliver skin benefits, including dry skin improvement. However, body washes can be less convenient to transport and are generally more expensive on a per use basis than commodity cleansing bars. As a result, body wash adoption tends to reflect countries' economic development status.

Types of body washes

Body washes currently available in the market generally fall into three distinct categories. Regular body washes are products whose primary function is to provide skin cleansing. As such, they are typically based on a relatively simple chassis, although fragrance is sometimes used to define product character or to provide a higher order benefit (e.g. lavender scent may be used to produce a calming effect during use).

Moisturizing body washes are intended to provide a dry skin improvement in addition to performing the base skin cleansing function. However, there are different ways to define dry skin improvement for moisturizing body washes. In some cases a product's benefit is judged relative to another (drying) personal cleanser and "improvement" amounts to producing less dryness than the benchmark. In other cases a product's benefit is judged relative to an untreated control and "improvement" reflects the effect of the product relative to the condition of untreated skin. Thus, moisturizing body

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washes can provide markedly different levels of dry skin improvement depending on the criterion used to judge their performance.

Finally, there are products that fall into a broad category best described as specialty body washes. These are extensions of regular and moisturizing body washes that contain ingredients intended to provide additional function or benefit. Examples include products that contain beads or other grit material (e.g. pulverized fruit seeds) to provide exfoliation and an enhanced dry skin benefit, and products that contain menthol or other sensates to provide a "cooling" or "tingling" sensation to the skin.

Major formula components of body washes

Water

Unlike their cleansing bar counterparts, body wash formulas contain a high percentage of water. This situation is a double-edged sword. On the one hand, eliminating the need to form materials into a bar that will hold its shape while maintaining good performance and wear characteristics removes a number of formulation constraints, and this introduces the possibility of incorporating relatively high levels of non-cleanser materials (e.g. benefit agents) into the formulation. On the other hand, the aqueous milieu present in liquid cleansers and body washes introduces issues not present in bars. For example, many benefit agents are lipophilic in nature and an improperly formulated liquid cleaner may exhibit phase separation or creaming, not unlike the separation of oil and water phases that occurs in some salad dressings. Chemical stability is also a consideration; the greater mobility afforded by a liquid environment increases the likelihood of molecular interactions, and water itself can participate in decomposition reactions (e.g. hydrolysis). An aqueous environment also increases the potential for microbial contamination. Thus, formulating a liquid cleanser or body wash presents a number of unique challenges, particularly if the product is intended to perform a function beyond simple cleansing such as delivering a benefit agent to the skin.

Surfactants

Surfactants are the workhorse ingredient in any personal cleansing product. Water is capable of removing some soils from the skin; however, sebum and many of the soils acquired on the skin through incidental contact or purposeful application (e.g. topical medicaments) are lipophilic in nature and are not effectively removed from the skin's surface by water alone. Surfactants, or surface-active agents, have a dual nature; part of a surfactant molecule's structure is lipophilic and part of it is hydrophilic. This structural duality allows surfactant molecules to localize at the interface between water and lipophilic soils and lower the interfacial tension to help remove the soil. Further, surfactants allow water to more effectively wet the skin's surface and to solubilize lipopilic soils after removal, which prevents the soils from redepositing on the skin during rinsing. Surfactants are also responsible for the formation of bubbles and lather, which most consumers view as necessary for effective cleansing.

As with cleansing bars, the surfactants used in liquid personal cleansers and body washes fall into two primary groups: soaps and non-soaps, also known as synthetic detergents or syndets. Soap is chemically the alkali salt of a fatty acid formed by reacting fatty acid with a strong base, a process known as saponification. The fatty acids used in soap manufacture are derived from animal (e.g. tallow) or plant sources (e.g. coconut or palm kernel oil). These sources differ in their distribution of fatty acid chain lengths, which determines properties such as skin compatibility and lather. Soap's properties are also affected by external factors such as water hardness; soaps are generally more irritating and lather and rinse more poorly in hard water. Some specialty body washes contain soaps derived from "natural" fatty acid sources such as coconut or soybean oil; these products will behave similarly to products containing soaps derived from traditional fatty acid sources.

Syndets, which are derived from petroleum, were developed to overcome shortcomings associated with soaps (e.g. the influence of water hardness on performance) and to expand the pool of available raw materials used in manufacture. Syndets vary widely in terms of their chemical structure, physicochemical properties, and performance characteristics, including skin compatibility. Syndets are not necessarily less irritating than soaps. Sodium lauryl sulfate is an example; many dermatologists view alkyl sulfates as model skin irritants. Most body washes are based on syndet surfactant systems, and because syndets have a wide range of performance characteristics, most body washes combine several surfactant types to achieve specific performance to the finished product. For example, alkyl sulfates, while having relatively poor skin compatibility, lather well. Combining an alkyl sulfate with an amphoteric surfactant such as cocamidopropyl betaine can improve both lather and skin compatibility. Thus, formulating a body wash with syndets involves choosing surfactants to optimize performance and aesthetics, balanced with cost considerations.

Skin benefit agents

Some body washes contain ingredients that are intended to provide skin benefits beyond simple cleansing. Dry skin, which is a pervasive dermatologic issue, is one of the most common benefit targets for body washes. Not surprisingly, moisturizing ingredients such as petrolatum, various oils, shea butter, or glycerin, which are found in leave-on moisturizers, are often used in moisturizing body washes. However, simply including a moisturizing ingredient in a

rinse-off product is not sufficient; the product must deposit an effective amount of the material on skin during the cleansing and rinsing process. As noted earlier, standards for judging moisturizing efficacy differ. Clinical testing shows that moisturizing body washes vary widely in their ability to provide a dry skin benefit, and that some may actually worsen dryness and irritation.

In addition to moisturizing ingredients to improve dry skin, body washes may also contain particulates such as beads or pulverized fruit seeds to aid exfoliation. A particulate's size, surface morphology (i.e. smooth or rough), and in-use concentration will determine its ability to provide this benefit. Finally, body washes may contain ingredients that are intended to protect from or to reduce the effects of environmental insults. As with moisturizing ingredients, an efficacious amount of these materials must remain on skin after washing and rinsing.

Other ingredients

Body wash formulas contain additional ingredients that act as formulation and stability aids. The addition of polymers and salt alter a product's viscosity, which can modify performance characteristics or improve physical stability. Feel modifiers such as silicones are sometimes used to improve the in-use tactile properties of body washes that deposit lipophilic benefit agents on skin. Chelating agents such as ethylenediamenetetraacetic acid (EDTA) and antioxidants such as butylated hydroxytoluene (BHT) and are added to improve chemical stability, and buffering a body wash formula to a specific pH value can help inhibit microbial growth and improve the product's chemical and physical stability.

Color and fragrance are an important part of the in-use experience for many body washes. Colors are US Food, Drug, and Cosmetic Act (FD&C) approved dyes and are usually present in relatively low amounts, so the likelihood of experiencing an issue with a body wash product because of dye is low. Fragrances are also usually present in relatively low amounts, although the apparent concentration may seem higher as a result of "bloom" that results from lathering a body wash on a mesh cleansing puff, the recommended application procedure for many of these products. The incidence of issues with modern fragrances is low. Some body washes incorporate natural oils to impart fragrance but these products are not necessarily without potential issues because some of these natural materials can cause sensitization.

In-use performance considerations for body washes

Cleansing ability

The mechanical action associated with applying a personal cleanser to the body helps to loosen and remove some soils, but surfactants are the primary agents responsible for aiding soil removal, particularly lipophilic soils. However, surfactants and the cleansing products based on them differ in their abilities to remove sebum and lipophilic soils [1]. These cleansing performance differences are a greater consideration in body washes than in bars because of the relatively lower surfactant concentrations present in the former compared with the latter.

Because lipophilic soils present the greatest cleansing challenge, oil-based makeup materials are often used as model soils in tests intended to measure cleansing efficiency. These materials are poorly removed from the skin by water alone and their inherent color makes them easy to detect visually or instrumentally and measure on the skin's surface.

To test the cleaning efficiency of various methods of skin cleansing, we conducted a study comparing a moisturizing petrolatum-depositing body wash, a syndet detergent bar, and water for cleansing ability. A commercial oil-based makeup product served as a model soil and was applied to discrete treatment sites on the volar forearms of light-skinned females. The makeup was allowed to dry for 15 minutes and baseline colorimeter (L*) values were recorded at each site. Lather was generated from each cleansing product in a controlled manner and applied to a randomly assigned site for 10 seconds with gloved fingers. Sites were rinsed with warm water for 15 seconds, allowed to air dry for 30 minutes then chromameter measurements were repeated. Data were analyzed by a mixed-model procedure.

The results show that water has little effect on removing the model soil from the skin and while the makeup used in this study is perhaps an extreme challenge, it nonetheless exemplifies why personal cleansing products are needed for soil removal. Not surprisingly, both personal cleansing products removed a significantly greater amount of the model soil than did water ($P < 0.01$), but the petrolatum-depositing body wash showed significantly greater makeup removal (i.e. cleansing efficiency) than the syndet bar (mean ΔL^* values of 5.2 and 3.2, respectively; $P < 0.02$). Thus, this study shows that a petrolatum-depositing body wash can clean efficiently and demonstrates that consumers are not restricted to the traditional bar form for their skin cleansing needs.

Consumer understanding and need for moisturizing body washes

Patients with dry skin that accompanies a dermatologic condition often require a high level of skin moisturization and may be willing to tolerate poor moisturizer product aesthetics (e.g. skin feel) to obtain relief. A recent habits and practices study among a group of 558 adult females demonstrates that a consideration of consumers' varied moisturization needs and their desired product aesthetics must be made in

order to create products that improve patient compliance. These participants answered questions that provided a range of information about their needs for body moisturization and their expectations for a moisturizing personal cleansing product (i.e. body wash).

Dry skin was a source of discomfort for a majority of participants; 62% said they were "very bothered" or "bothered" by discomfort due to dry skin, while 20% said they were "not bothered" by discomfort due to dry skin. Dry skin also drove these consumers to apply leave-on moisturizers; 68% said they "strongly agreed" or "agreed" that they needed to use a moisturizer every day because of their dry skin, while only 16% "disagreed" that their dry skin necessitated daily moisturizer application. With regard to moisturizing cleanser needs, 97% of the participants stated that they want more moisturization from their personal cleansing product. The needs fell into three groups that aligned with self-perceived body skin type. Women in one group (very dry skin, 32% of the population) want a body wash product that delivers a high level of moisturization and a substantial skin feel; women in a second group (dry skin, 35% of the population) want a body wash product that delivers a moderate level of moisturization and a somewhat perceivable skin feel; and women in a third group (combination skin, 22% of the population) want a body wash that provides a low level of moisturization, rapid absorption of the moisturizing agent, and no residual skin feel.

This study is just one example of work conducted to understand female consumers' needs and expectations with regard to dry skin and moisturization. Traditionally, the needs and expectations of their male counterparts were at best little studied and poorly understood, or at worst assumed to be the same as those of females. To gain insights into male consumers' needs we conducted a habits and practices study among an adult panel representative of the US adult population comprising 303 males and 313 females. As in the study above, participants responded to a series of questions related to attitudes towards body skin condition, body skin care habits and practices, and attitudes towards various cosmetic interventions.

This consumer research showed a strong contrast between the sexes in terms of their usage of products to care for their body skin. Males were on the whole less likely to use a treatment on their body than were females. However, dry skin ranked high on the list of body skin care needs for both sexes. Moisturizer application was identified as the best treatment for dry skin, but males were less likely to apply moisturizer to their bodies than were females because of a perceived time constraint. Skin-feel parameters were also more important to males than females; males wanted to feel clean, not sticky or greasy. Surprisingly, the study results indicate that males are more likely to seek help from a dermatologist for their dry skin than females.

Moisturization from body washes

Dry skin on the body is a finding in many dermatologic conditions and the results presented in the previous section show that even in the absence of frank skin disease dry skin ranks as one of the most common body skin complaints for both sexes. Skin that is dry can itch, and flaking on "problem" areas such as legs, knees, and elbows is aesthetically unpleasing and can negatively impact self-confidence. Dry skin worsens with age, and low relative humidity, certain medications, and excessive hot water exposure are among the factors that can exacerbate dry skin. Personal cleansing products are also frequently cited as agents that cause or worsen dry skin via removal of essential skin lipids following excessive cleansing or cleansing with "harsh" surfactants.

Dry skin signals that there is an insufficient level of moisture in the stratum corneum. Dermatologists often recommend application of leave-on moisturizers to relieve symptoms and to provide an environment in which the skin can repair stratum corneum damage associated with dry skin. However, surveys show that a high percentage of dermatologists believe that their (female) patients do not moisturize as recommended, a lack of convenience being cited as the primary reason for the perceived non-compliance. This pattern is consistent with the results found in our consumer habits and practices research.

Coupling moisturization with an existing habit such as showering can improve compliance but, as noted earlier, there are different ways to define a moisturization or dry skin improvement benefit, and simply including a moisturizing ingredient in a body wash formula does not guarantee that it will deposit on skin or remain in a sufficient amount after rinsing to provide a benefit.

We conducted a leg wash clinical study using the industry standard method (leg controlled application test) comparing the dry skin improvement efficacy of a water control and three marketed moisturizing body wash products [2]. Treatment sites on the legs were washed in a controlled manner once daily for 7 days with the randomly assigned treatments. Expert visual scores and instrumental measurements collected at baseline and study end were used to assess the change in dry skin condition produced by the treatments. Expert scoring shows a range of skin effects from these moisturizing products (Figure 11.1). Two of the body washes delivered significant ($P < 0.05$) improvement in dry skin relative to the water control, while one of the products had little effect on visible dry skin. Skin capacitance measurements showed the former body washes improved stratum corneum hydration ($P < 0.05$), while the latter reduced stratum corneum hydration relative to the control ($P < 0.05$), i.e. it dried the skin. Expert erythema scoring and transepidemal water loss (TEWL) showed a similar pattern; two of the body wash products improved skin condition relative to control, while the third significantly ($P < 0.05$) increased erythema and TEWL. This highlights the importance of

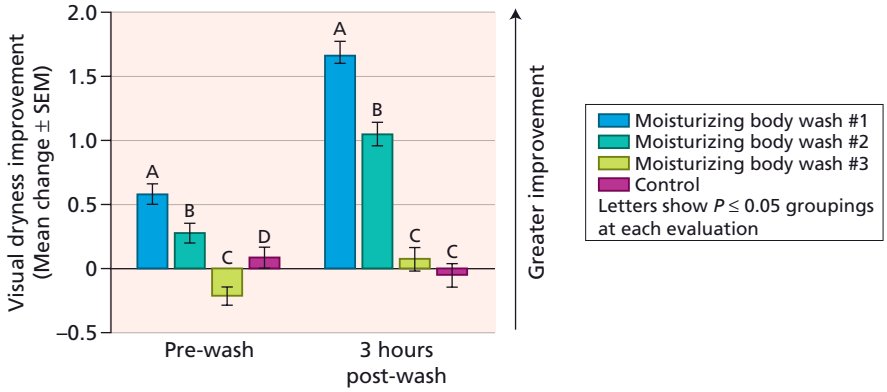

Figure 11.1 Expert dryness scores after 7 days of once-daily washing with marketed body wash products. The results show marked differences in the products' abilities to provide a dry skin improvement (i.e. a skin moisturization benefit).

understanding how products that are labeled as "moisturizing" perform clinically whenever possible. Simply recommending that a patient should use a moisturizing body wash may not produce an optimal benefit, and the wrong product recommendation could actually worsen skin condition.

The consumer research presented in the previous section also highlights the need for personal cleansing products that deliver different levels of moisturization and different use aesthetics. Many personal cleansers are available in versions that ostensibly are designed for different skin needs, but such products often involve relatively minor changes in formulation and performance. Body washes, because of the greater formulation flexibility they offer, provide an opportunity to develop product versions that offer different levels of performance to meet specific needs. For example, the habits and practices study conducted among females identified three primary consumer groups in terms of body skin moisturization and body wash performance needs. Various body wash products have been created that offer differences in moisturizer level and dry skin improvement benefit across versions in order to meet these needs.

Who will benefit from using body washes?

The body wash is a relatively new-to-market personal cleanser form that will initially appeal to users with practical concerns or to users seeking experiential benefits such as better lather and in-use scent intensity, which are often greater than a bar can deliver. Where body washes really distinguish themselves from traditional bar forms, however, is in their ability to provide higher order skin benefits. As we have shown, some body washes can provide a marked skin moisturization benefit that can affect not only the quantity but also the morphology of dry skin flakes (Figure 11.2). A large segment of the population can benefit from using this type of personal cleansing product. However, the following are two examples of conditions that may derive a particular benefit from a moisturizing body wash.

Ashy skin

African-Americans and other dark-skinned individuals frequently suffer from ashy skin, a condition in which the skin's surface appears grayish or chalky as a result of excessive dryness. The condition is often exacerbated by soap bar use which is common among this population. Moisturizers or other oils can provide temporary relief but, as discussed earlier, convenience often limits willingness to use leave-on products. Petrolatum is an effective moisturizer but neat application to the skin is limited by both convenience and esthetics. However, a petrolatum-depositing body wash may circumvent these issues while still delivering a skin benefit.

To test this hypothesis, we conducted a study among a group of 83 African-American females who normally applied a leave-on moisturizer to relieve their ashy skin [3]. Subjects used a randomly assigned syndet bar or a moisturizing petrolatum-depositing body wash product for daily home showering for a 4-week period. Endpoint evaluations showed that the body wash produced significantly greater dermatologist-scored dry skin improvement and subject satisfaction for items such as ashy skin improvement and reducing itchy/tight feeling. Perhaps most importantly, subjects assigned to the petrolatum-depositing body wash noted marked improvement in their level of satisfaction with the appearance of their leg skin, their level of confidence in letting others see their legs, and in feeling good about themselves because of the appearance of their leg skin (Figure 11.3). These results indicate that proper personal cleanser choice can not only improve the physical symptoms of dry skin but also impact how users feel about themselves.

Atopic dermatitis

Atopic dermatitis is a chronically relapsing skin disorder that currently affects an estimated 10% of children and adults in the Western Hemisphere and whose incidence is growing worldwide. Symptoms include xerosis, skin hyperirritability, inflammation, and pruritus. Personal cleansing products are viewed as a triggering factor for atopic dermatitis and dermatologists frequently recommend that their patients avoid

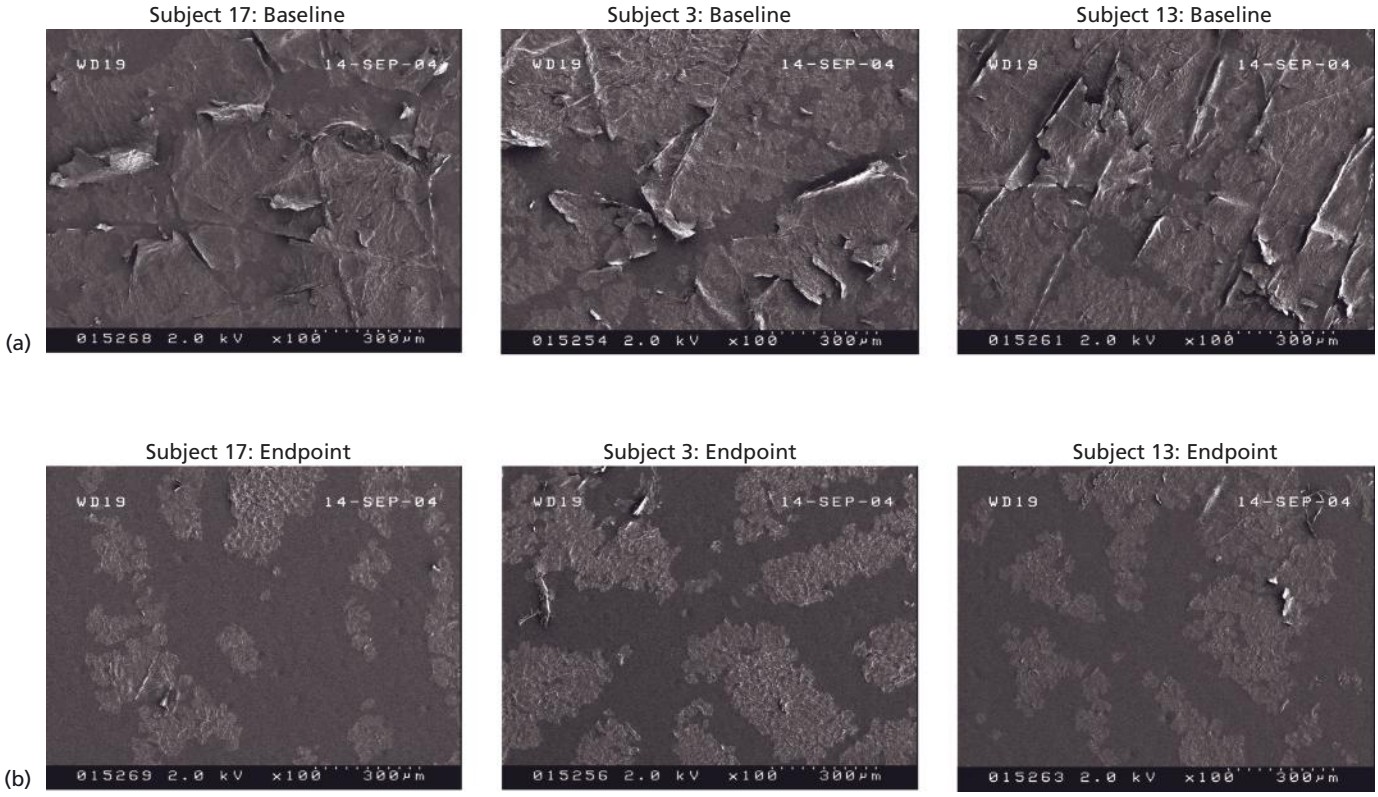

Figure 11.2 Scanning electron microscope (SEM) photomicrographs of skin flakes adhering to tape strips taken from subjects' legs before (a) and after (b) using a petrolatum-depositing body wash for 3 weeks. Baseline samples show numerous large, thick, dry skin flakes; endpoint samples show fewer and thinner flakes.

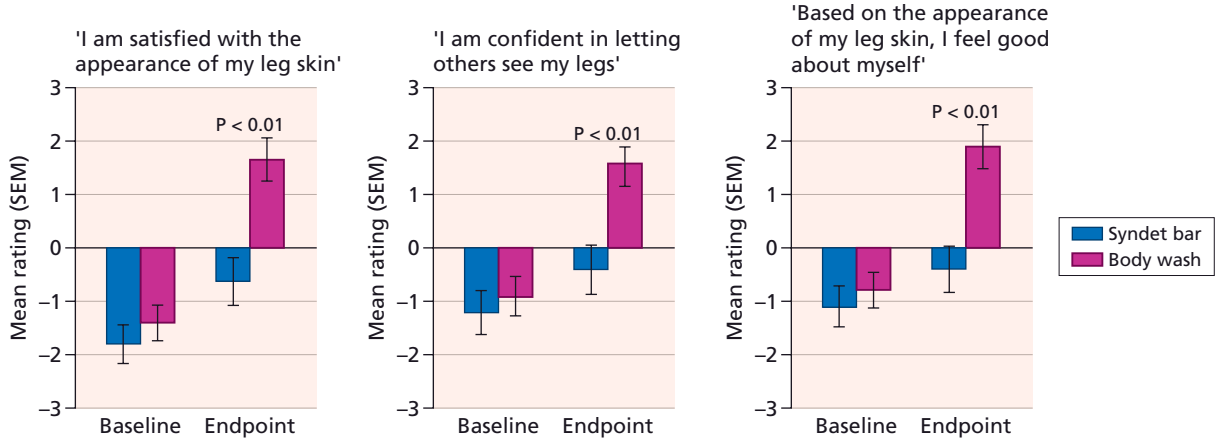

Figure 11.3 Responses to psychosocial questions answered by African-American subjects before and after using a syndet bar or petrolatum-depositing body wash for 4 weeks. Items were rated on a +3 (strongly agree) to –3 (strongly disagree) scale. Ratings were not significantly different at baseline ($P \geq 0.48$); endpoint ratings given subjects assigned to use the body wash were significantly better than those given by subjects assigned to use the syndet bar ($P < 0.01$).

harsh cleansers. Therapy typically involves application of a prescription topical corticosteroid, using a mild cleanser for bathing or showering, and applying a moisturizer within 3 minutes of the bath or shower to seal in moisture [4]. The latter suggests that a moisturizing body wash may be ideally suited as a therapeutic adjunct in atopic dermatitis.

We conducted two studies among subjects undergoing treatment for mild to moderate active atopic dermatitis to examine the effect of using a moisturizing petrolatum-depositing body wash for cleansing. In both studies a moisturizing syndet bar, which is often recommended to patients undergoing therapy, was used as a control. In one study both cleansers were paired with 0.1% triamcinolone acetonide cream. Subjects applied the topical corticosteroid as directed and used their assigned personal cleanser for daily showering. After 4 weeks SCORAD for subjects who used the moisturizing body wash was significantly ($P < 0.01$) lower than for subject who used the bar. Subjects using the body wash also noted significantly ($P < 0.01$) greater improvement in skin dryness and itching.

The second study again involved subjects with mild to moderate active atopic dermatitis, but in this case subjects assigned to use the petrolatum-containing moisturizing body wash were prescribed a medium potency topical corticosteroid, while subjects assigned to use the moisturizing syndet bar were prescribed a standard high potency topical corticosteroid [5]. At study end the dermatologist investigator judged that subjects assigned to cleanse with the petrolatum-containing moisturizing body wash showed a significantly ($P < 0.01$) greater incidence of disease clearing than did subjects who used the syndet bar. The greater therapeutic response observed in the body wash group is important, but so is the fact that it was achieved using a lower potency topical corticosteroid, which can potentially reduce cost and the risk of steroid-related side effects. Subjects in the moisturizing body wash group also rated their skin condition better for a number of parameters related to their atopic condition. The results from both these studies indicate that therapeutic response in atopic dermatitis is influenced by personal cleanser choice and again highlight the importance of personal cleansing product choice when treating skin disease.

Conclusions

Body washes represent a new possibility in personal cleansing products, not only because of their ability to provide effective cleansing and deliver an improved in-use experience (e.g. lather amount, rinse feel, scent display) compared with bar cleanser forms, but also because they have a potential to improve skin condition by mitigating dry skin. Moisturizing body washes are in a position to meet a key consumer need for both men and women – dry skin improvement on the body. However, delivering a skin benefit from a rinse-off product is challenging and the product must leave an effective amount of benefit agent on the skin after washing and rinsing. Not surprisingly, moisturizing body washes vary widely in their ability to deliver a benefit and recommenders must understand these differences when evaluating moisturizing body wash products.

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Chapter 12: Facial cleansers and cleansing cloths

Erik Hasenoehrl

Procter & Gamble Co., Ivorydale Technical Center, Cincinnati, OH, USA

BASIC CONCEPTS

- The four goals of facial cleansing are: (1) to clean skin, removing surface dirt and all make-up; (2) to provide a basic level of exfoliation; (3) to remove potentially harmful microorganisms (bacteria); and (4) to cause minimal damage to the epidermis and stratum corneum.
- Cleansing can occur by three means: (1) cleansing by chemistry; (2) cleansing by physical action; and (3) in many cases, cleansing by a combination of both chemistry and physical action.
- Chemical cleansing occurs via surfactants categorized into four primary groups: cationic, anionic, amphoteric, and non-ionic.
- Facial cleansers can be categorized as follows: lathering cleansers, emollient cleansers, milks, scrubs, toners, dry lathering cleansing cloths, and wet cleansing cloths.

Introduction

Facial cleansing is not only a means to remove dead skin, dirt, sebaceous oil, and cosmetics, but also a first step in an overall skincare routine, preparing skin for moisturizers and other treatments. Facial cleansing also has an important role, well beyond skincare, in psychological well-being, helping to provide a ritualistic sense of renewal and rejuvenation [1].

Many cleansing technologies – ranging from water to a traditional bar of soap – are available to meet the facial cleansing needs of different skin types and soil loads. This chapter provides an overview of the many specialty facial cleanser technologies available, discusses technologies best suited to each skin type and cleansing need, and provides an in-depth understanding of substrate-based facial cleansers, which represent the newest technology available for facial cleansing.

History

Facial cleansing is observed in the animal kingdom and existed well before *Homo sapiens* inhabited Earth. Early facial cleansing consisted primarily of a quick splash or rinse of the face with cold water. In fact, this habit can still be observed in the animal kingdom today among many primates [2].

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The first recorded use of facial cleansing utilizing more than water was among the Ancient Egyptians in 10 000 BC [3]. Egyptians were heavy users of makeups made from a base of metallic ores which contained natural dyes for color; this mixture was then painted onto the face. In this period, Early Egyptians typically bathed and removed makeup in a river. Their cleansers consisted of animal fat mixed with lime and perfume, and were similar to some of the homemade natural soaps in use today. Facial cleansing and body cleansing were done with the same soap.

More recently, over the past 20 years, specialty facial cleansers have become quite mainstream, a result of an explosion in cleansing technology which has led to a multitude of high-quality, relatively low-cost cleansers. Most of the technical development have focused on three primary areas:

1 Better removal of exfoliated skin, dirt, soil, excess sebaceous oil, and makeup;

2 Synthetic surfactants that induce less skin barrier damage and are thus less likely to dry skin; and

3 Incorporation of cleansing chemistry onto cleansing cloths.

Patients tend to take more care with cleaning and maintaining their face than the rest of their bodies. As such, consumer product companies have developed many different technologies and cleansing forms that benefit different facial skin types, cleansing rituals, and soil loads. Because there is such a broad array of cleansing forms, specialty facial cleansers has become a very fragmented category of products, which utilize more different technologies than most other cleaning applications. Although a wide range of products is available, these products share four common traits:

1 To clean skin (removing surface dirt and all make-up);
2 To provide a basic level of exfoliation;
3 To remove potentially harmful microorganisms (bacteria); and
4 To cause minimal damage to the epidermis and stratum corneum.
Additionally, facial cleansers are required to remove a myriad of chemicals and biologic materials, ranging from the latest waterproof makeup to excess skin oils and upper layers of stratum corneum.

Function

It is well understood that the use of harsh surfactants and/or overwashing skin can result in overremoval or distortion of stratum corneum and intercellular lipids, which can lead to reduced skin barrier function [4].

While the wide array of facial cleanser technologies all provide basic levels of skin cleansing, they all clean skin slightly differently. The mechanisms by which cleansing is accomplished can be grouped into three main categories:
1 Cleansing by chemistry;
2 Cleansing by physical action; and
3 In many cases, cleansing by a combination of both chemistry and physical action.

Chemistry of cleansing

Two classes of chemicals are used in facial cleansers and are responsible for the cleaning effect: surfactants and solvents. Both of these types of chemicals interact with dirt, soil, and skin to remove unwanted material. Surfactants and solvents work via two different chemical mechanisms to effect removal of these materials. Understanding these mechanistic differences provides dermatologists with the insight needed to prescribe a cleansing regimen based on individual patient needs.

Surfactants

Surfactants or "surface acting agents" are usually organic compounds that are amphiphilic, meaning they contain both hydrophilic groups and hydrophobic groups. The combination of both hydrophilic and hydrophobic groups uniquely makes surfactants soluble in both oil and water.

Surfactants work by reducing the interfacial tension (the energy that keeps water and oil separated) between oil and water by being adsorbed at the oil–water interface. Once adsorbed at the interface, cleaning surfactants assemble into a low-energy aggregate called a micelle. Surfactant needs to be present at high enough concentration to form a micelle, a level called the critical micelle concentration (CMC), which is also the minimum surfactant concentration required to clean sebaceous oil, cosmetics, etc. When micelles form in water, their tails form a core that encapsulates an oil droplet, and their (ionic/polar) heads form an outer shell that maintains contact with water. This process is called emulsification.

Surfactants clean skin by emulsifying oily components on the surface of skin with water. Once emulsified, the oil can be easily rinsed from skin during the post wash or rinse process. The stronger the surfactant, the more hydrophobic material removed, the greater the potential skin damage from excessive removal of naturally occurring skin lipids, and the greater the ensuing compromise of optimal skin barrier function, therefore correct and careful formulation of these surfactants is required to ensure proper mildness. Recently marketed products show that with careful formulation very strong surfactants such as sodium laurel sulfate (SLS) can be well tolerated by skin. All surfactant-based cleansers require water and generally include a rinsing step. They are best suited to removal of oily residue.

Unfortunately, two problems have been associated with cleansing with surfactants (one real and one largely folklore). First, because of their powerful cleansing action, overuse may completely eliminate the protective lipid barrier on the surface of skin, resulting in irritation and dryness. Second, for years consumers have heard negative stories regarding the alkaline (pH around 9) nature of these products. Wrongly assuming that because skin pH is about 5, washing with these high pH surfactants can lead to an increase in skin pH. Recent data suggest that the skin's natural buffering capacity is more than adequate to eliminate any unwarranted impact of the pH of these products.

Classic surfactants used in facial cleansers are categorized into four primary groups: cationic, anionic, amphoteric, and non-ionic.
1 *Cationic surfactants* used alone are generally poorly tolerated, and are now rarely used in skincare products without carful formulation into coaceravate systems.
2 *Anionic surfactants*, such as linear alkyl sulfates, consist of molecules with a negatively charged "head" and a long hydrophobic "tail." Anionic surfactants are widely used because of their good lathering and detergent properties.
3 *Amphoteric surfactants*, such as the betaines and alkylamino acids, are well tolerated, lather well, and are used in facial cleansers.
4 *Non-ionic surfactants*, such as polyglucosides, consist of overall uncharged molecules. They are very mild (tolerated better than anionic, cationic surfactants on skin), but do not lather particularly well.

Some surfactants are harsh to the skin while others are very mild. Because of the wide variety of available surfactants, not all surfactant-based cleansers are the same. It is important for patients to use products that best fit their skin type. Today, most cleansers use synthetic surfactants.

Solvents

A solvent is a liquid that dissolves a solid or another liquid into a homogeneous solution. Solvent-based systems clean skin by dissolving natural sebaceous oil and external oils applied to skin via cosmetics and similar materials. Solvents work under the chemical premise that "like dissolves like." Solvents can be classified broadly into two categories: polar and non-polar. Typical non-polar solvents used in facial cleansing, such as mineral oil or petrolatum, are from the oil family, whereas typical polar solvents used in cleansing, such as isopropyl alcohol and ethanol, are from the alcohol family. Solvent-based cleansers are usually not used in conjunction with water; rather, they are applied and then "wiped" off with a tissue or cotton ball.

Solvent-based cleansers should be chosen carefully on the basis of cleansing need. Non-polar solvents work well for removing oil-based makeups and cosmetics but have little effect on water-based formulations. Similarly, alcohol-based systems work well on water-based makeups. It is also important to note that alcohol-based systems can dry skin, a benefit for younger consumers with acne-prone skin but a potential disadvantage for older consumers and those with dry skin. However, oil-based products can leave a greasy or oily residue, which is beneficial for consumers with dry skin, but undesirable for those with normal to oily skin types. Choosing a solvent-based cleanser based on skin type is critical.

Physical cleaning

An alternative to chemical cleansing is physical cleaning of skin. Essentially, physics, primarily in the form of friction, has an important role in cleansing. In facial cleansing, friction is generated primarily by the direct interaction of a washcloth, tissue, cotton ball, or cleansing cloth and the surface of skin. Friction works to help dislodge soils, as well as increase the interaction of chemical cleaning agents (surfactants and solvents) with soils. The role of friction is covered in more detail in the section on substrate cleansers.

Types of facial cleansers

Seven primary and popular forms of facial cleansers exist (other rarely used forms exist but are not covered in this chapter). These cleansers can be categorized as follows: lathering cleansers; emollient cleansers; milks; scrubs; toners; dry lathering cleansing cloths and wet cleansing cloths. Each form is described in detail below. A summary of cleansers, technologies, and uses can be seen in Table 12.1.

Lathering cleansers

While lathering cleansers constitute one broad classification, they all have one unique characteristic that separates them from all other cleansing forms – they all generate lather when used in the cleansing process. Typically, these cleansers are formulated with a surfactant level greater than the CMC such that excess surfactant can incorporate air and form lather. Additionally, these cleaners contain surfactants that have short hydrophobic chains; shorter chains enable faster and higher levels of lather. Most lathering cleansers sold today utilize synthetic surfactants that have been especially designed to be mild to skin. These synthetic surfactants have little interaction with skin lipids and therefore produce substantially less skin damage than naturally derived surfactants. However, this quality also compromises to a small extent their capability to remove oil-soluble makeups.

Many classes of surfactants are used in facial cleansers; two common ones include sarcosinates and betaines [5]. Even formulations with newer surfactants tend to exhibit some skin barrier damage in clinical studies. Thus, lathering cleansers are generally warranted for patients with normal to oily skin or those who are removing a high cosmetic load (makeup, lipstick, or other cosmetic load). Interestingly, there is a strong consumer bias towards lathering cleansers because high levels of lather provide a very strong signal to consumers that the cleanser is working.

Lathering cleansers clean through the chemical process of emulsification, this simply means that the cleanser emulsifies dirt and oils, by suspending or emulsifying materials, thus permitting them to be removed from skin during the rinse process. Many formulators of lathering cleanser products have tried to incorporate skin conditioning technologies that enable deposition of skin conditioners onto skin. Unfortunately, these technologies have generally been less successful at providing skin benefit ingredients than other cleansing forms.

Emollient cleansers

Emollient cleansers are a milder alternative to lather cleansers. Although they clean via emulsification, they do not form lather in the presence of water. Surprisingly, however, they do form a structure that suspends dirt and makeup within formulation. Typically, these cleansers provide a very high level of soil removal without drying the skin to the same degree as lathering cleansers. Emollient cleansers generally consist of a special formulation of lathering surfactants in which either lathering is suppressed by an oil (e.g. mineral oil) or the surfactant forms a complex with another charged molecule to inhibit the formation of the air–water interface necessary to provide lather.

Clinically, emollient cleansers are generally less harsh on skin than lathering cleansers. However, consumers sometimes complain that emollient cleansers leave a residual film on skin that does not satisfy some cleansing expectations. Typically, these cleansers are best suited to those patients with high cleansing needs who also have dry skin.

Scrubs

Facial scrubs are a subset of emollient cleansers. They generally contain small particles of natural or polymeric ingredients. Scrubs are intended to provide a deep cleansing experience including a higher level of skin exfoliation from abrasion with the particles. A non-exhaustive list of natural scrub particles includes seeds of many fruits (e.g. peach, apple, apricot), nut shells (e.g. almond, walnut), grains (e.g. oats, wheat), and sandlewood. Synthetic scrub particles include polyethylene or polypropylene beads. Because of their abrasive nature, patients with sensitive skin may not want to use these as their daily use cleanser; for those with sensitive skin they should be used once or twice a week in addition to normal cleansing routines.

Cleansing milks

Milks are a form of cleaner that is generally not used in conjunction with water. Because they are not used in conjunction with a water rinse, cleansing milks are ideal for depositing beneficial agents, such as humectants, petrolatum, vitamins, and desquamatory ingredients, onto the skin. These cleansers are a good choice for cleaning dry or other diseased skin. One drawback is that the residual ingredients left on skin can make skin feel as though cleansing is incomplete. Milks work by dissolving, as opposed to emulsifying, oils and dirt. Typically, they are applied like a lotion and then wiped off with a tissue, cotton ball, or towel.

Toners

Toners are a class of facial cleansers formulated to clean skin and shrink pores. This class of cleanser utilizes solvency as the primary mode of cleaning. Toners are usually applied with a physical substrate, such as cotton balls, tissues, or wash cloths; however, some newer toners can be sprayed on and wiped off. In most cases, toners are used in the absence of water. Toner formulations generally utilize alcohol as the solvent of choice and some level of humectants.

Toners usually exist in three strengths:

1. *Mild:* 0–10% alcohol, refresher;
2. *Medium:* 10–20% alcohol, tonic; and
3. *Strong:* 20–60% alcohol, astringent.

More recently, some companies have developed two-phase toners, which consist of a solvent and an immiscible oil formulated to provide astringent benefits while minimizing the dry skin feeling. Typical uses of toners are makeup removal and pore cleaning associated with acne care. Toners are popular with teenagers and young adults because of the perceived acne benefits and pore tightening associated with this technology.

Substrate cleansers

Over the years, facial cleansers have evolved from traditional bar soaps, to milder synthetic detergents, and, most recently, to cleansing cloths (disposable substrates such as a non-woven material) pretreated with active cleansing and conditioning ingredients. Introduced in the early 2000s, substrate-based cleansers are a relatively new addition to the cleansing technologies available to dermatologists and consumers. These cleansers combine low levels of mild detergents with conditioning ingredients to provide state-of-the-art cleansing and exfoliation with unprecedented mildness [6]. Further, cleansing cloths can be designed to meet the specific needs of different skin types.

The substrates used in cleansing cloths generally consist of natural fibers (e.g. cotton); synthetic fibers (e.g. rayon, polyester terphalate [PET] or polypropylene); or a blend of one or more of these fibers. Depending upon the fibers used and the non-woven manufacturing process, the substrate texture can be tailored to meet differing expectations from very soft to rough, meaning that different exfoliation levels can be delivered to the consumer. Technology introduced in 2007 further improves exfoliation and cleansing capabilities by printing a polymer on the surface of a non-woven cloth.

The mechanism by which cleansing is accomplished with a cloth is different from that with the liquid cleansers described above. In the case of substrate cleansers, cleaning is driven by a combination of physics (friction from interaction with cloth and skin) and chemistry (either emulsification or dissolution). This combined action offers several key advantages for product formulation and use. Because of the form itself, the cloth can contain a low level of surfactants. Further, utilizing multiple cleansing mechanisms allows formulators the flexibility to customize formulations that contain smaller amounts of chemical ingredients. As a result, substrate-based cleansers can be formulated with as little as 25% of the surfactant used in traditional liquid cleansers (P&G Beauty, Cincinnati, OH, USA, Comparison of surfactant level in Olay Foaming Face Wash, and Olay Daily Facials; unpublished data). For the patient, use of products with combined cleaning mechanisms results in much cleaner skin. Also, lower surfactant levels translate to less skin damage. (True when directly comparing skin damage versus surfactant level of identical surfactants. Surfactant type alone has a large impact on skin damage and must be considered as well as surfactant level when recommending a cleanser.) Another key trait of substrate cleansing cloths is that dirt, makeup, and oil are picked up by and contained within the cloth. The visible dirt and oils on the cloth provide a subtle clue to patients that the cleansing step is complete, reducing overcleansing, another contributor to skin damage.

Despite the low level of surfactants in substrate cleansers, these products can still generate a generous lather via the cloth structure, which incorporates air as the lather is generated. The low levels of mild detergent combined with the ability to deposit conditioning agents directly onto the skin result in improvement in the skin's overall condition beyond

basic cleansing. Finally, the different cloth textures allow individualized, but gentle, exfoliation which removes skin flakes for a more even skin surface. This combination of benefits can eliminate the need for other specialty cleansing products such as toners and exfoliators. Two popular forms of substrate-based cleansers exist today:

1 Dry cleansing cloths; and
2 Wet cleansing cloths.

The mechanism by which cleansing is accomplished with a cloth is different from that with the liquid cleansers described above. In the case of substrate cleansers, cleaning is driven by a combination of chemistry (either emulsification or dissolution) and physics (friction from interaction with cloth and skin). This combined action offers several key advantages for product formulation and use. Utilizing multiple cleansing mechanisms allows formulators the flexibility to customize formulations that contain lower levels of chemical ingredients. As a result, substrate-based cleansers can be formulated with as little as 25% of the surfactant used in traditional liquid cleansers [7]. For the patient, use of products with combined cleaning mechanisms results in much cleaner skin. Also, lower surfactant levels translate to less skin damage. Another key trait of substrate cleansing cloths is that dirt, makeup, and oil are picked up by and contained within the cloth. The visible dirt and oils on the cloth provide a subtle clue to patients that the cleansing step is complete, reducing overcleansing, another contributor to skin damage.

Dry lathering cleansing cloths

In early 2000, the advent of daily cleansing cloths ushered in the next generation of facial cleansers. Dry cleansing cloths consist of lathering surfactants that have been incorporated in the manufacturing process onto a disposable wash cloth. The patient is instructed to wet the cloth at the sink with warm water and rub to generate lather. Therefore, these products provide a rich, creamy lather like one would find in the lathering cleansers described earlier. Additionally, many of these products contain and deposit on to stratum corneum moisturizing ingredients such as petrolatum and glycerin. These products became an instant success because they combine multiple skin care benefits into one product:

1 High level of cleansing;
2 High level of exfoliation;
3 Minimal reduction in skin barrier function;
4 Rich lather; and
5 In the case of at least one product, significant moisturization [6].

A unique advantage of dry cleansing cloth technology is that the product can be manufactured so that different ingredients can be placed in different "zones" on a cloth. This simple approach enables skilled formulators to use ingredients that are not compatible in a liquid cleanser. Olay Daily Facials is one example in which the cleansing surfactant, skin conditioner, and fragrance are applied separately and to different zones of a cloth. This permits the product to deposit conditioning ingredients directly onto skin during the washing procedure, thus delivering unprecedented conditioning benefits from a lathering cleanser. In fact, cleansing cloths are the only specialty cleansing technology that is proven to provide the cleanest skin and improve skin barrier function. Studies have shown that separate addition of petrolatum onto a cleansing cloth provided unparalleled hydration and transepidermal water loss (TEWL) benefits and resulted in a smoother skin surface, a more compact stratum corneum, and well-defined lipid bilayers at the surface of the stratum corneum [8].

Wet cleansing cloths

Wet cleansing cloths are traditionally manufactured and shipped to the consumer in their wet state. They originated from disposable wipes technology that was initially developed for removal of excrement and other soils from babies during diaper changes. Wet cloths are used without additional water in both the cleaning and rinsing (wiping off) rituals. Wet cloths are generally of the non-lathering variety and as such can be used as a "wipe-off" product, as opposed to being rinsed with water. The advantage of wet cloths is that small amounts of beneficial ingredients, such as humectants and lipids, are left behind on the skin. This property makes wet wipes one of the most effective cleansing products for patients with dry skin.

Guide to selecting facial cleansers

Recommending a facial cleansing regimen can be a daunting task given the multitude of cleansing forms available. To choose the most appropriate cleanser, physicians should consider skin type, skin problems, and any skin allergies.

The following section provides a short reference guide and tools to help in selection of cleansers based on patient skin type, cleansing need, and preference. The selection guide is broken into three parts or strategies:

1 Selection based on skin type;
2 Selection based on cleansing form; and
3 Selection based on skin problems.

Selection based on skin type

The first step in selecting a facial cleanser is to assess the patient's skin type and to categorize it as dry, oily, or normal. Once skin type has been determined, assess the skin for any problems, such as acne, excessive flakiness, and dryness. Table 12.1 systematically lists the main facial cleansers covered in this chapter, and highlights the key characteristics of each cleanser and the best cleanser for each skin type.

Table 12.1 Cleanser technology and skin types.

Type of facial cleanser	Primary cleaning mechanism	Key characteristics	Primary recommended skin type
Liquid lathering cleansers	Emulsification	Forms lather when wet	Oily
Emollient cleansers	Emulsification	Non-lathering	Dry
Scrubs	Emulsification	Non-lathering, particulates provide exfoliation benefit	Dry, flakey
Milks	Dissolution	High conditioning, generally not used with water	Dry skin
Toners	Dissolution	Low viscosity liquid, pore tightening	Oily/young Acne prone
Dry cleansing cloths	Emulsification and physical removal	Provides multiple benefits: cleansing, conditioning, exfoliating, toning	All skin types
Wet cleansing cloths	Dissolution and physical removal	Provides multiple benefits: cleansing, conditioning, exfoliating, toning. Generally not used with water	Dry skin

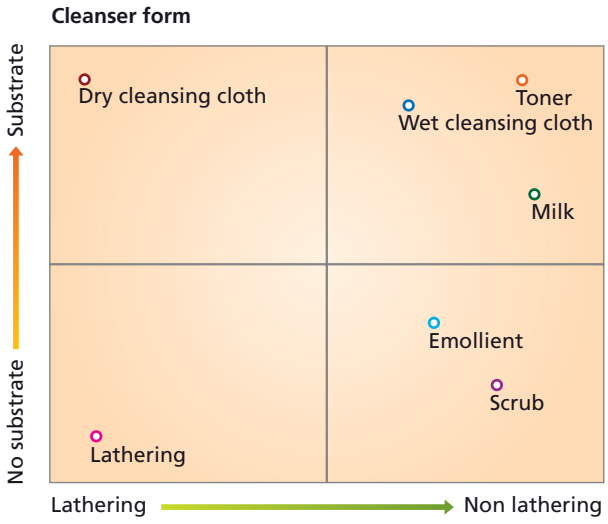

Figure 12.1 One of the main cleansing ritual preferences: no substrate/substrate and lathering/non-lathering.

Selection based on cleanser form or cleansing ritual

The second strategy for selecting facial cleansers is to first assess a patient's cleansing ritual preference. Figure 12.1 depicts one of the main cleansing ritual preferences: no substrate/substrate and lathering/non-lathering. To use this approach most effectively, first, identify the quadrant of Figure 12.1 that best describes the patient's ritual preference, and then use Table 12.1 to select a facial cleanser that best matches the patient's skin type. This may be the best approach to selecting a cleanser is when compliance with skincare is critical.

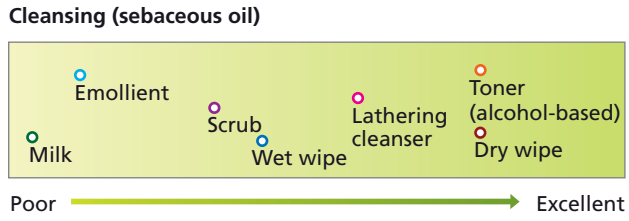

Figure 12.2 Products for the removal of excess sebaceous oil.

Selection based on skin problems

In many cases, cleanser selection may be somewhat subjective. The following figures provide a hierarchy of the primary benefits associated with facial cleansers ranked by cleanser type. The benefits described in this section are cleaning excess sebaceous oil, cleaning dirt and makeup loads, exfoliation, and mildness to skin. Considering these benefits when prescribing a cleansing routine may prove useful in providing a cleanser that fully meets patient expectation and needs.

Cleaning excess sebaceous oil

Removal of excess sebaceous oil is a significant concern of teens and young adults. Cleansing of sebaceous oil is best accomplished with either lathering products that emulsify the oils or toners that are specifically formulated to solubilize sebaceous oil. These products and can also give users a sense of control over oily skin by providing pore tightening benefits (Figure 12.2).

Cleaning dirt and makeup

One of the primary benefits of a facial cleanser is removal of high makeup loads and dirt. By a wide margin, dirt and makeup removal is best performed by substrate cleansers. The high cleansing capability of these cleansers is brought about by their capability to provide both physical and chemical cleaning, in addition to the substrates' ability to trap and hold dirt and oil within their fibers (Figure 12.3).

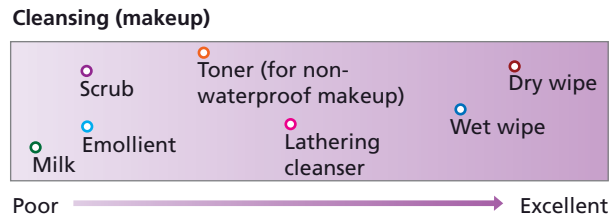

Figure 12.3 Products for the removal of dirt and makeup.

Exfoliation: removing dry, dead skin cells

When high exfoliation is required, because of aging or for other reasons, products that provide physical cleansing are an appropriate choice because they also provide the highest level of exfoliation. Exfoliation is brought about by physical abrasion, which removes the top layers of skin. As a side note, most cleansers provide low to insignificant levels of exfoliation; thus, if exfoliation is the main skin need, a substrate-based cleanser is highly recommended (Figure 12.4).

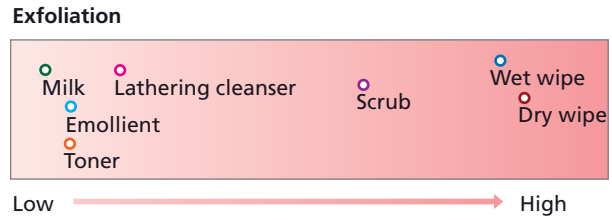

Figure 12.4 Products for the removal of dry, dead skin cells.

Cleanser mildness

For much of facial cleansing history, cleanser mildness was a significant concern. Now, with new surfactant and cleansing technologies, most specialty facial cleansers (with the exception of toners) provide close to neutral or better mildness. Figure 12.5 ranks cleansing forms for skin for patients for whom dry skin is a key complaint.

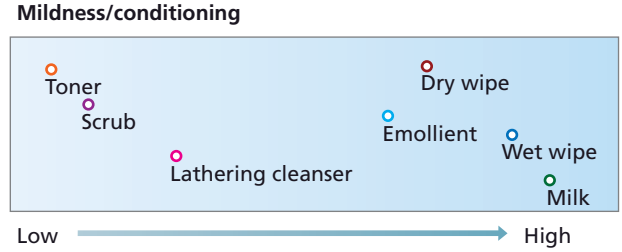

Figure 12.5 Products for patients for whom dry skin is a key complaint.

Conclusions

Many different facial cleansing forms exist today. All can be categorized on the basis of three factors:

1 The type of chemistry used, either surfactant or solvent based;

2 Whether or not the cleansing form creates lather; and

3 Whether or not the cleansing form incorporates physical cleansing as well as chemical cleansing.

All of these facial cleansing forms provide the basic level of cleansing required to maintain healthy skin; however, different skin types benefit from different cleansing forms, and patient preference drives usage and compliance.

The future of the facial cleansing category is bright. Significant innovation is expected to continue for the foreseeable future, particularly in substrate cleanser applications and formulations for removing the new and more durable makeups and mascaras that are entering the market. Technical development will continue to focus on low damage to skin and improved delivery of specially directed skin ingredients during the cleansing process.

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Chapter 13: Non-foaming and low-foaming cleansers

Duncan Aust
DFB Branded Pharmaceuticals, Fort Worth, TX, USA

BASIC CONCEPTS

- Effective cleansing can be achieved without foam production.
- Non-foaming and low-foaming cleansers are appropriate for all skin types.
- Mild surfactants are key to minimizing barrier damage.
- Non-foaming and low-foaming cleansers are typically water-based.

Introduction

The effective and appropriate use of a suitable skincare regimen is critical to maintaining healthy skin. This cleansing regimen becomes more important in dermatologic disease, where an inappropriate skin care regimen can impede positive treatment outcomes [1]. Cleansing is the first step in managing any dermatologic disease and the right choice of cleanser can have a considerable impact on treatment success.

The earliest cleansers were used by the Babylonians around 2200 BC. The Egyptians subsequently combined animal and vegetable oils with alkaline salts to create soap-like substances. Cleansers then evolved to contain salts of fatty acids derived by reacting fat with lye in a process known as saponification, which marked the beginning of currently available foaming soap-based cleansing systems.

Non-foaming cleansers were developed in the 2nd century in the form of cold creams and milks. The Greek physician Galen is considered the father of cold cream, because he combined olive oil, beeswax, water, and rose petals. More modern formulations also add borax.

There are now many different classes of cleansers; however, this chapter focuses on non-foaming and low-foaming cleansers. It outlines the different types of non-foaming cleansers and how they vary from their regular foaming, liquid, or bar counterparts. It also outlines the most logical choice of non-foaming or low-foaming cleansers for certain skin types and discusses the merits of various cleanser formats.

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Types of non-foaming and low-foaming cleansers

Many consumers mistakenly believe foaming or lathering is a requirement for effective cleansing. However, what is not broadly understood is the fact that, even in the absence of foaming, cleansing can still occur. This is the fundamental premise upon which non-foaming and low-foaming cleansers are based.

There are two primary classes of non-foaming and low-foaming cleansers: aqueous or water-based formulations, which may or may not require water for cleansing, and a second class of waterless cleansers. The majority of non-foaming and low-foaming cleansers are water-based formulations containing several ingredients: water, surfactants, moisturizers, stabilizing agents, preservatives, fragrances, and dyes (Table 13.1). Key to the efficacy of these aqueous-based cleanser formulations are three primary ingredients; water, surfactants, and humectants.

Surfactants

The most important ingredient in the majority of cleansing systems is the surfactant. A surfactant is a chemical that stabilizes mixtures of oil and water by reducing the surface tension at the interface between the oil and water molecules and enhances the formation of foam and its colloidal stability. Surfactants perform two functions in a cleanser. First, they stabilize the cleanser formulation by allowing the oil phase and water phase to coexist in a stable system. Without surfactants, it would be impossible create single-phase formulations. Second, and most importantly, surfactants are required to meet the performance requirements of the cleanser.

Surfactants can generally be divided into five classes: anionic, amphoteric (zwitteronic), cationic, non-ionic, and

Table 13.1 Types of non-foaming and low-foaming cleansers.

Cleanser types	Physical forms	Key ingredients
Foaming	Lotions	Surfactants, water, foam boosters, humectants, preservatives
	Bars	Surfactants, waxes, binders, filers
	Body washes	Surfactants, water, foam boosters, humectants, preservatives, dyes
Low foaming	Lotions	Surfactants, water, humectants, preservatives
	Gels	Surfactants, water, humectants, preservatives
	Creams	Surfactants, water, humectants, preservatives
Non-foaming	Cold creams	Water, oil, wax, surfactants
	Waterless cleansers	Solvent/alcohol, water, surfactant
	Thin lotion/milks	Water, moisturizers, oils, surfactants, solvents, preservatives
	Two phase	Oil, water, solvent/alcohol, dyes

polymeric surfactants. The anionics are characterized by their good foaming and cleansing abilities, but can be too irritating for the skin. As a result, anionics are combined with milder surfactants or conditioning agents. Non-ionics and polymerics tend to be the mildest surfactants and are used in "gentle" cleansing systems. Traditional cationics can be irritating, but new classes have been introduced, rivaling the performance of the non-ionics. The final class, amphoterics, are also mild but this property can differ with pH.

Over the last 40+ years, there has been an effort to develop "gentler acting" surfactants, hence the large number of non-ionic surfactants currently available. The non-ionic surfactants are the basis for a new group of low-foaming, reduced irritation cleansers and may be combined with the polymeric or amphoteric classes. Examples of mild surfactants and surfactants with low irritation include sulfoacetates, acyl sarcosinates, amphoproprionates, alkanolamides, alkylglucosides, and the original mild surfactant cocamidopropyl betaine.

Low foam production

A major drawback of most mild synthetic surfactant systems is poor lather performance. Generally, the longer the carbon backbone of the surfactant, the less irritating the molecule. However, this mildness is often obtained at the expense of effective cleansing and lathering. In fact, many modern cleansers supplement their formulations with "foam boosters" simply to enhance the appearance of foam. These additional ingredients are not required for cleansing, have no cleansing properties, and are there solely to meet consumer expectations. A careful balance is required between mildness and lather.

Mildness

The potential for irritation can be reduced by appropriately matching surfactants. For example, sodium lauryl sulfate (SLS), an anionic surfactant with a high index of irritation, has been shown to elicit less irritation when combined with sodium laureth sulfate (SLES) [2]. Balancing the level of surfactants in the formulation to ensure effective cleansing while not having a detrimental effect on skin barrier lipids and proteins is important.

Other ingredients can be added to the cleanser formulations to mitigate any detrimental effects. Some of the milder cleansers contain humectants, such as glycerin, to attract water to the skin. Other humectants, such as butylene glycol or propylene glycol, have been used but are less favored than glycerin. Hyaluronic acid, which has the capacity to bind many times its own weight in water, is very expensive and seldom used. The use of humectants in low-foaming and non-foaming cleansers is now commonplace in high end products.

In addition to humectants, other skin barrier building ingredients can be used. For example, ceramides and plant extracts with reported antioxidant, anti-irritant properties can be used. However, it is challenging to ensure that these ingredients are delivered to the skin in a cleanser that is rinsed away. Utilizing controlled or sustained release systems can increase ingredient delivery. One example of a controlled release delivery system employed in a cleanser system is the use of a multivesicular emulsion. This emulsion is composed of multilamellar particles, which allow for the sustained release of substances such as ceramides, glycerin, and hyaluronic acid [3].

The mildness of a cleanser is dependent upon many important factors, most notably the choice of other

Table 13.2 Principal cleanser types.

Cleanser types	Advantages	Disadvantages	Skin type best suited
Non-foaming	Gentle Non-drying Low levels of surfactants	Limited cleansing ability for oily types Limited rinsibility with cold creams Can leave behind residue	Dry to normal
Low foaming	Gentle Non-drying Easy to remove Low levels of surfactants	Limited cleansing ability for oily types	Dry to normal
Bar	Excellent cleansing ability	Can strip barrier of essential oils and lipids Drying Can raise pH of skin Primarily composed of anionic surfactants	Oily
Foaming liquid	Good cleansing ability Easy to remove	Can strip barrier of essential oils and lipids	Normal to oily

ingredients in the formulation and the product's pH [4,5]. Two of the most irritating classes of ingredients used in formulations are fragrances and preservatives. Often the combination of fragrances and high levels of surfactants gives way to a high irritation index. Several studies have correlated a product's poor performance in patch testing experiments to the combined effects of surfactants and allergens [6,7]. Because of these effects, mild cleanser products are fragrance free; however, preservatives remain a necessary part of the formulator's arsenal to ensure the products remain free from microbial contamination.

Waterless cleansers

Other means of skin cleansing not involving traditional surfactants is with the use of solvents to dissolve oils and sebum. These waterless facial cleansers are aqueous-based alcoholic preparations, typically containing diluted isopropyl alcohol and a small amount of surfactant. Sebum is soluble in alcohol and glycol-based solvents. These cleansers are convenient to use without access to water, and can be effective in patients with very oily skin; however, long-term usage may be harmful to the skin barrier.

Other alternative cleansing systems include two-phase systems, where the oil and water–solvent phase do not mix in the formulation and remain as two distinct layers. These systems are mixed by shaking prior to use. They have the advantage of low surfactant concentrations but do not have broad consumer acceptability.

Lipid-free cleansers

A new class of cleansers for normal to oily skin is referred to as a lipid-free cleanser. Lipids are defined broadly as fat-soluble, naturally occurring molecules, such as fats, oils, waxes, sterols, monoglycerides, diglycerides, and phospholipids. Lipid-free cleansers have the advantage of not depositing any lipid-like materials on the skin surface. They balance their cleansing and moisturizing ability. In lipid-free cleansers, moisturization is performed by replacing sebum with synthetic oils along with the addition of humectants, such as glycerin. While good for normal to oily skin, lipid-free cleansers may not be the ideal choice for dry skin. Table 13.2 highlights the principal cleanser types: bar, foaming liquid, non-foaming, and low-foaming (regular and lipid free).

Mechanisms of cleansing

In the case of the non-foaming cleansers, especially cold creams, the primary mode of action is dependent on the formulation's ability to bind sebum, dirt, bacteria, and dead skin cells. Cold cream formulations are water-in-oil emulsions (W/O) where the external phase of the emulsion is the hydrophobic or oily component and the water is partitioned as small droplets in the internal phase. It is because of the external oil phase that cold creams bind well to sebum, dirt, and cosmetics with easy removal by wiping.

Certain lighter lotions or milks also work along a similar principle, although they differ from cold creams because they are primarily oil-in-water (O/W) emulsions. Upon application to the skin surface, the oil phase droplets "seek out" sebum on the surface of the skin, entrapping it, and facilitating its removal with gentle wiping or water rinsing. These lighter lotions also differ from cold cream by containing some classic surfactants. The surfactants are used to maintain a stable emulsion with an internal oil phase and external aqueous phase, but do not provide any foaming

capability. These cleansers have limited cleansing ability and are not the most effective class of cleansers for oily skin, but work well on dry to normal skin.

Cleansing skin barrier damage

The cutaneous effects of surfactants are dependent upon the type, duration of exposure, and concentration [8,9]. Many different surfactants affect the stratum corneum, or outer layer of the epidermis, causing dryness, damage to the barrier function of the skin, irritation, itching, and redness [10]. Surfactants interact with various components of the stratum corneum, including proteins and lipids. Interaction occurs with corneocytes or protein complexes made of threads of keratin, as well as with lipids. In the case of the corneocytes, the surfactants bind to these proteins allowing them to swell and making it possible for other ingredients in the formulation to penetrate into the lower layers of the skin where they can cause itching and irritation. The irritation properties of surfactants have been demonstrated to be related to the mechanisms by which surfactants interact with the stratum corneum [11].

As for lipids, the interaction of surfactants with lipids in the stratum corneum is still not fully understood. Surfactants may get between the lipid bilayers causing increased permeability and even disruption of the bilayer [12]. Surfactants can also cause damage to the lipid structures themselves. Surfactants reduce the amount of lipids in the skin and disrupt skin barrier function by removing these lipids as the cleanser is used. It is not always the surfactants themselves that result in irritation, but other ingredients contained in the formulations (e.g. fragrances and preservatives). The surfactant effect on barrier function opens a pathway for the damaging effects of other ingredients. Obviously, compromising the skin barrier is best avoided as a compromised barrier has been correlated with skin disease including, psoriasis, atopic dermatitis, and other ichthyoses [13].

Conclusions

In conclusion, the advantages of non-foaming and low-foaming cleansers are mildness. The disadvantages are related to little foaming capability, but this should not be perceived by the consumer as representing ineffective cleansing. Cleansers that leave a "squeaky clean" feel to the skin surface and produce abundant foam may not be the best choice in patients with sensitive skin needs. Non-foaming and low-foaming cleansers achieve a delicate balance between skin cleansing and tolerability.

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Chapter 14: Liquid hand cleansers and sanitizers

Duane Charbonneau

Procter & Gamble Co., Health Sciences Institute, Mason, OH, USA

BASIC CONCEPTS

- The hands are a common site for microbial contamination.
- Hand cleansers and sanitizers are designed to reduce transient microbes on the skin surface with the intent of reducing the spread of infectious disease.
- Hand cleansing products include liquid soaps with antimicrobial agents, alcohol-based hand sanitizers as well as non-alcohol-based hand sanitizers.
- Hand hygiene technologies have decreased nosocomial infections.
- Hands with damaged skin harbor more transient organisms than hands with healthy skin.

Introduction

Hand washes and hand sanitizers are designed to reduce transient microbes on the skin with the intent of reducing the spread of infectious disease. This class of products includes liquid soaps; liquid soaps with antimicrobial agents, alcohol-based hand sanitizers as well as non-alcohol-based hand sanitizers.

Over the past 20 years there has been an increasing concern regarding infectious disease within the community and hospital. In the USA, deaths from infectious disease are ranked sixth among all deaths according to statistics published by the Centers for Disease Control and Prevention. Nosocomial infections are one of the most frequent and severe complications of hospitalization. Nosocomial infections are the fourth leading cause of death in Canada and account for approximately 100 000 deaths annually in the USA [1,2]. These statistics are extremely sobering in light of all the advances made in modern medicine today.

Several mitigating factors are responsible for the rising numbers of infection rates within the community as well as the hospital setting. First, is the changing nature and ranges of pathogens to which individuals within the community and hospital are exposed. Pathogens such as rotavirus, *Campylobacter*, *Legionella*, SARS, *Escherichia coli* O157 (*E. coli*), and norovirus were not commonplace prior to 1980. Additionally, methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* were largely considered hospital problems. Today, community-acquired MRSA (CA-MRSA), norovirus, and new more virulent strains of *C. difficile* (02) are circulating within the general populous.

Second, there are cultural changes that have a role in this increased infection burden, such as reduced hospital stays, in home care for elderly, ease of travel, and a large population of immunocompromised individuals.

Third is the diminished research aimed at the identification of new antibiotics. It is no longer economically feasible for pharmaceutical companies to develop and register novel antibiotic technologies. This situation is further exacerbated by the increasing development of antibiotic resistance among common pathogenic microorganisms.

With all of these issues, the mechanisms of dealing with infectious disease for the future must fall on prevention strategies in place of treatment regimes. Because hand contact has a crucial role in the transmission of infectious agents, it is imperative that consumers and hospitals have effective hand hygiene technologies.

Hand microbiota

Microbes that inhabit the hand are generally divided into two categories: transient and resident flora (Figure 14.1). The transient flora is microbes that inadvertently become attached to the hands following touching of contaminated surfaces; for example, a raw food item, or, as in the case of healthcare workers, an infected wound or body fluid. Several studies have documented the potential of this transfer of transient flora from hands to other parts of the body within an individual or alternatively between individuals. The classic example is the work by Hendley and Gwaltney [3] which demonstrated the importance of hand-to-hand transmission of the common cold virus.

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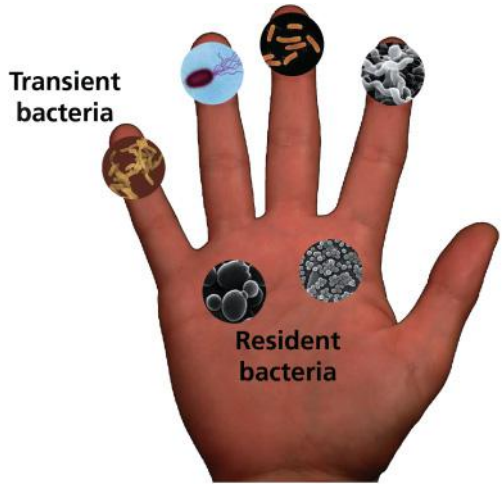


Figure 14.1 The common flora of the hand. Transient flora are those microorganisms that are picked up from the environment. Resident flora are the microorganisms that routinely inhabit the skin.

Table 14.1 Constituents of the hand resident flora.

Organism
Acinetobacter baumannii
Acinetobacter johnsonii
Acinetobacter lwoffi
Corynebacterium spp.
Enterobacter agglomerans
Enterobacter cloacae
Klebsiella pneumoniae
Propionibacterium acnes
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Staphylococcus warneri
Streptococcus mitis
Streptococcus pyogenes

The resident flora of the hand is defined as the complex community of microbes that consistently inhabit the hand and routinely are not washed off with non-medicated soaps. A summary of the bacteria that have been reported to be isolated as resident flora is presented in Table 14.1.

Unfortunately, few studies have been undertaken to clearly define the role that these microbes have in health and disease. However, it is speculated that the resident skin microbes are as essential to the health of the skin as the gut microorganisms are to overall health of the individual [4]. The resident flora provides positive health benefits by inhibition of pathogens, immune modulation, and improving the integrity of the skin barrier.

Although the resident skin flora usually has an essential role in protecting the host, under certain circumstances the resident flora can be pathogenic itself. For example, *Staphylococcus epidermidis*, an important member of the resident skin flora, is also a common pathogen associated with wound infections. Further, it is estimated that approximately 32% of the population carries the common pathogen *Staphylococcus aureus* as a member of the skin resident flora [4].

It would appear that frequent exposure to certain transient microbes may lead to them becoming established as a constituent of the resident flora. For example, studies have shown that nurses performing similar tasks within a hospital will have some similarities among their resident flora; while those assigned to different tasks will have different constituents within their resident flora [5,6]. Furthermore, it has recently been shown that homemakers often carrier bacteria within their resident hand flora that are identical to those environmental isolates identified within the home [7].

In terms of hand hygiene, the majority of hand soaps as well as hand sanitizers are primarily targeted toward reducing the level of transient bacteria and viruses on hands. Some products provide only immediate activity (e.g. alcohol hand sanitizers), whereas others provide immediate and residual protection benefits (e.g. triclosan-containing hand sanitizers). Residual protection provides benefits in between product usage preventing re-establishment of transient flora.

Hand hygiene

Since the mid 1800s with the ground breaking work by Professor Ignaz Semmelweis demonstrating a reduction in puerperal sepsis following the institution of hand hygiene protocols, the concept of hand hygiene as means of infection control has been well accepted. In the late 1970s–1980s our understanding that the part hands play in the transmission of bacterial and viral pathogens including the common cold have become well documented [8,9]. Today, hand washing using soap and water or hand antisepsis using hand sanitizer products is the cornerstone of many infection control programs.

Hand washing and hand antisepsis guidelines were published by the Association for Professionals in Infection Control (APIC) in 1988 and updated in 1995 [10]. The most recent updates were published in 2002 by the Hygiene Task Force composed of members of APIC, Center(s) for Disease Control (CDC), Healthcare Infection Control practices

Advisory Committee (HICPAC), Society for Healthcare Epidemiology of America (SHEA), and Infectious Diseases Society of America (IDSA) [11]. Since 1995 these various guidelines recognize the utility of hand washing with antimicrobial containing soap as well as the use of waterless hand sanitizers. The Food and Drug Administration's (FDA) Food Code contains specific hand hygiene guidance for retail and food service workers describing when, where, and how to wash and sanitize hands. Hand sanitizers, meeting specific criteria described in section 2-301.16 of the Food Code, may be used after proper hand washing in retail and food service [12].

Hand hygiene compliance

The importance of hand washing is well understood by professional and non-professionals; unfortunately, observational studies that measure compliance based on these standards are, at best, disappointing. Hand hygiene compliance studies estimate that healthcare workers are 40% compliant and food service workers are 30% compliant with standard guidelines [13,14]. A recent observational study demonstrated that fewer than 50% of hospital healthcare workers were observed to wash their hands after toileting [15]. Within the general population, observational studies have clearly demonstrated a gender difference among hand washing compliance. A large American Society for Microbiology study demonstrated that 88% of women and only 66% of men wash their hands after visiting the toilet. Other studies have shown that hand washing compliance is inversely proportional to education levels, indicating that the understanding of guidelines is not the issue [16]. Because hand washing compliance is low there is a need for hand sanitizers, especially those with persistent benefit, to be included in hand hygiene strategies.

Hand washing techniques

Hand washing when done properly is considered to be the gold standard for removing transient pathogenic bacteria from the hands. The best accepted hand washing protocol established by the CDC is described below.

Proper hand washing with soap and water

- Wet your hands with warm, running water and apply liquid soap or use clean bar soap. Lather well. Rub your hands vigorously together for at least 15–20 seconds.
- Scrub all surfaces, including the backs of your hands, wrists, between your fingers and under your fingernails.
- Rinse well.
- Dry your hands with a clean or disposable towel.
- Use a towel to turn off the faucet.

The most effective mean wash time is considered to be 15–20 seconds, but observational studies on subjects within healthcare and community settings indicate that the average hand wash time lasts less than 8 seconds. This would imply that as currently practiced the removal of transient microorganisms from the hands is suspect at best. Quantitative studies within a community setting have substantiated this hypothesis. A study conducted by Larson *et al.* [17] in homemakers measured mean colony-forming units count of 5.72 before washing and 5.69 after. These results indicated that the hand washing technique as practiced was ineffective.

A final factor for consideration is that of pH. The low pH of the hands has a crucial role in the innate antimicrobial hostility of the hand surface. The pH of the hands is approximately 4–5 routinely; however, the alkalinity of soaps can result in an increase in the skin pH [18]. This poses a concern because some of the antibacterial characteristics of skin are minimized. In one report, pH increased 0.6 to 1.8 units after hand washing with plain soap and then gradually declined to baseline levels over a period of 45 minutes to 2 hours [18]. Recently, a hand sanitizer has been introduced that provides antibacterial efficacy using triclosan formulated into a low pH matrix. This product maintains the low pH of the hand surface for hours. This imparts not only an immediate antimicrobial benefit but a persistent one as well [19].

Several studies have demonstrated that damaged hands harbor more transient microorganisms than healthy hands [20]. Repeated hand washing with soap and water removes the protective lipid layer which is followed by transepidermal water loss and cutaneous signs of redness, scaling, and possibly dermatitis. The use of alcohol-based hand sanitizers can also lead to dehydration of the skin as well as lipid removal and skin damage which may lead to increased colonization by transient flora. Recent investigations have shown that only subjects with healthy skin achieved appropriate levels of decontamination with plain soap and water [20]. Thus, individuals with damaged hands will require more robust antimicrobial formulations.

Measurements of efficacy

Studies demonstrating the efficacy of antimicrobial hand soaps and sanitizers toward removal of transient microbes can be divided into three categories:

1 *In vitro* potency and spectrum of activity;
2 *In vivo* models with artificial inoculate; and
3 Clinical studies demonstrating efficacy.

In vitro measurements

In terms of the *in vitro* measures of efficacy, classic microbiologic protocols of minimum inhibitory concentration (MIC) and time kill studies are usually conducted with bacteria and viruses of interest. The relevance of these *in vitro*

measurements for products of this nature has been a debate within the research community for decades. The primary information garnered from these studies only provides insights into the potency and spectrum of activity of a formulation within the test laboratory setting.

Investigators have also relied on artificial substrates to model removal of transient flora from hands. In these model systems either pig skin or an alternative skin substrate mimic is utilized to model the hand. Bacteria or viruses are inoculated onto the substrate prior to treatment. Measurements of microbial reductions are made following the treatment and efficacy is calculated by comparison with either an untreated control or placebo. Recently, some researchers are using similar models to assess the residual benefits of these formulations. The waterless alcohol-based hand sanitizer technologies have little to no residual benefit versus the triclosan-containing low pH hand sanitizers which provide immediate as well as residual benefit (2008 Nonprescription Medicines Academy).

In vivo models with artificial inoculate mimic transient flora

Both in Europe and the USA, there are efficacy standards for antimicrobial soaps and hand sanitizers. In both geographic regions, the tests necessary to fulfill these regulatory requirements involve artificially inoculating subject's hands with large inoculums of indicator bacteria. This is followed by treatment, neutralization of the active ingredient, and enumeration of remaining viable bacteria.

The methods most widely accepted in Europe are EN 1499 for antimicrobial hand soaps and EN 1500 for leave-on hand sanitizers. In both of these test protocols, 12–15 subjects wash their hands with a plain soap and water. The hands are then contaminated by having the subject immerse their hands half-way to metacarpals in a 24-hour broth culture of a non-pathogenic strain of *E. coli*. Following drying, bacterial recovery is achieved by kneading the fingertips and palms separately into 10 mL Trypticase soy broth plus neutralizers. The hands are removed, disinfected, and again contaminated. The treatments are then applied for 30–60 seconds either with or without a rinsing step depending on product type (rinse-off or leave-on). Post-treatment bacteria are recovered as described above. Extracted bacteria are enumerated using traditional microbiologic plating techniques. In these European tests, efficacy is determined versus internal standards. For EN 1499, antimicrobial hand soaps must provide a superior log reduction to that achieved using a plain soap (sapo kalinus) following a 60-second treatment. When evaluating leave-on products such as hand sanitizers with EN 1500 procedures, the product must deliver a benefit not less than that observed with a 60-second application of 60% 2-propanol.

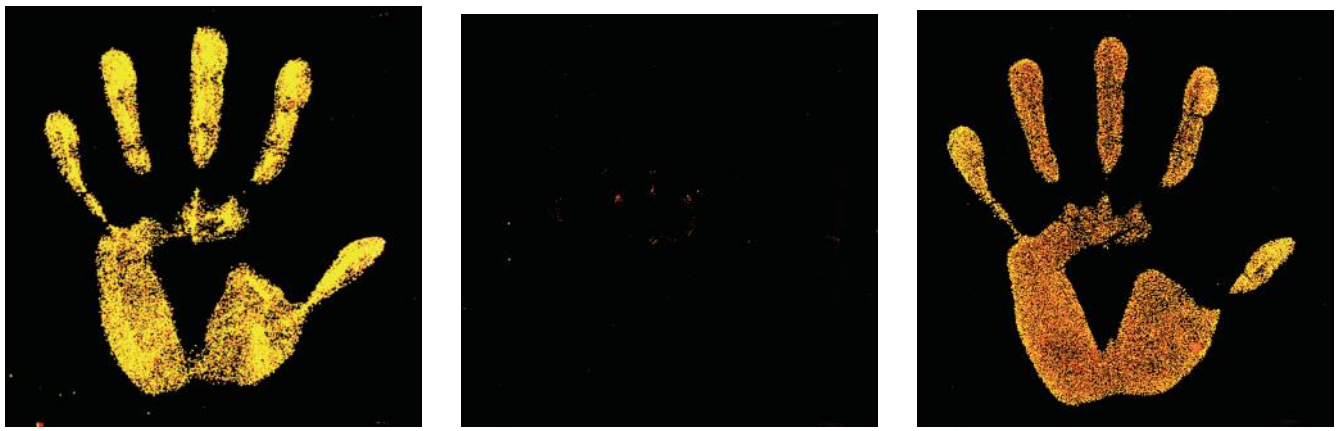
In the USA, antimicrobial soaps and sanitizers are regulated by the FDA's Tentative Final Monograph for Healthcare Antiseptic Drug Products (FR 1994). The standard method used to evaluate formulations is the American Society of Testing and Materials E 1174. In this test, subjects refrain from utilizing any antimicrobial products for 1 week prior to the start of the study ("washout period"). At the initiation of the study, the subjects perform a cleansing wash to eliminate any residual transient bacteria. The subjects' hands are then contaminated with 4.5–5.0 mL of a 24-hour broth culture of either a non-pathogenic *E. coli* or *Serratia marcescens*. Bacteria are then recovered by separately placing each hand into a glove containing 75 mL sampling solution plus neutralizers. The hand is massaged for 1 minute and bacteria are enumerated using traditional microbiologic plating techniques. This enumeration serves as the baseline measurement. The subjects then perform another cleansing wash and are reinoculated. Following this reinoculation the treatment is applied as described by the manufacture for either an antimicrobial soap or leave-on hand sanitizer. After the treatment is completed the bacteria are again recovered from the hands using the glove method and this is called Test Wash 1. This is followed by another cleansing wash. Once this cleansing wash is complete a cycle of inoculation followed by treatment is performed 10 consecutive times and bacteria are recovered at the 10th cycle. In this protocol, there is no internal standard. The success criteria are determined by log reduction versus the baseline measurement. In Wash 1, a product must achieve a minimum of a 2-log reduction, and at Wash 10, the product must deliver a 3-log reduction versus baseline.

Methodology concerns

There is a great deal of critique of these standard methods. First and foremost, these European and US protocols utilize treatment times and typically volumes of product that are far outside of the norm. In the case of the ASTM E1174, there is concern that bacteria are sampled from areas of the hands not involved in transmission such as the back of the hands. An additional concern is the appropriateness of these inocula to the real world situation. In the natural setting, transient bacteria would rarely be present without being incorporated into a soil matrix.

To address this issue, investigators have developed methodologies that incorporate the use of a soil matrix such as chicken or hamburger in place of marker bacterial organisms and focused attention is paid to the palms of the hands [21,22]. In the presence of a greasy soil matrix such as chicken, the alcohol-based hand sanitizers lack appreciable efficacy, whereas those containing more potent antimicrobial actives such as triclosan and benzalkonium chloride demonstrate a higher level of effectiveness (Figure 14.2).

In addition to these standardized methodologies, other protocols designed to mimic transient flora have been presented within the literature. The most utilized method is commonly referred to as the fingerpad method [23]. In this



(a) (b) (c)

Figure 14.2 Effects of different hand sanitizers on greasy soil. Bacterial growth has been colorized. (a) Untreated. (b) Triclosan-based. (c) Alcohol-based.

method, subjects who have previously refrained from using antimicrobial products have their fingerpads contaminated with either bacteria or viruses. The fingerpads are then treated with test product and the bacteria or viruses are enumerated. Recently, authors have utilized this test to evaluate the residual activity of a hand sanitizer. In this test the fingerpad was treated with the sanitizer and subsequently challenged with bacteria 3 hours later [19]. This study demonstrated that the hand sanitizer provided protection from microbial challenge for up to 3 hours post application. Other models have also been described in the literature with the aim of assessing residual antimicrobial activity as well as transfer of microbial agents. One such method involves the ability of antiseptic hand products to interrupt the transfer of microorganisms from fingerpads to hard surfaces under controlled pressures [24].

Resident flora

For consumer or common healthcare, antimicrobial hand soaps and hand sanitizers various methods have been developed to look at the impact of these products on the resident flora. One commonly used method is the Cade test which measures the impact of several washes over a period of 5 days [25]. This test, like the Health Care Personnel Handwash test, begins with a washout period. This is followed by a 5-day baseline period and samples are collected over 2 days to control for day-to-day variations. Following this baseline, subjects are instructed to use the product multiple times daily. Subjects are sampled for 2 days during the treatment phase. Efficacy is determined by comparisons between the baseline and treatment phases.

The antimicrobial efficacy of surgical hand antiseptics is determined according to a European standard (prEN 12791) and a US standard (TFM). The two methods differ in several ways as shown in Table 14.2.

Because of these differences, Kampf *et al.* [26] have stressed the need to evaluate potential products using both methodologies to assure efficacy. Overall, the model systems described above have been very helpful for the determination of efficacy for various antimicrobial hand soaps and hand sanitizers. However, it must be pointed out that these models are not always indicative of efficacy under real use conditions.

Table 14.2 US and European standard methods.

Difference	US method	prEN 12791
Product application	Hands and lower forearm	Hands only
Number of applications	11 over 5 days	Single application
Sampling times	0, 3, 6 hours post-application	0, 3 hours post-application
Sample method	Glove juice	Fingertip sampling
Success criteria	Absolute bacterial reduction	Non-inferiority to reference standard

Effectiveness of hand hygiene in the community setting

Unfortunately, clinical trials of hand hygiene regimes are complex and expensive to execute. Community intervention studies have been limited in scope and have delivered mixed and sometimes inconclusive results. Comprehensive reviews of these studies have resulted in less than favorable outcomes in terms of the quality and the conclusions derived [27]. Reduction in gastrointestinal illnesses associated with handwashing have ranged from −10% to 57%. Unfortunately, only three out of the five studies that evaluated gastrointestinal illness produced statistical significance. In these three

studies, the magnitude of the impact was approximately 50% reduction in the incidence of illness. The impact of hand hygiene on respiratory illness is more limited. The magnitude of the overall impact of current available studies has been estimated to be an approximate 23% reduction in the incidence rate of respiratory infections. Thus, current data implies that hand hygiene has its largest impact on gastrointestinal versus respiratory illness. A recent meta-analysis by Aiello *et al.* [28], using hand hygiene intervention studies, indicated that overall hand hygiene reduces the incidences of gastrointestinal illness by 31% (95% CI = 19–42%) and, to a lesser extent, respiratory illness by 21% (95% CI = 5–34%).

There are many more studies that examined the impact of alcohol-based hand sanitizers on subsequent infection rates. The conclusion by Meadows and LeSaux [29] was that the data were of poor quality and that more rigorous intervention studies were needed. The current studies have demonstrated a reduction in the incidence of gastrointestinal illness from 0 to 59%. The magnitude for respiratory illness and infection and/or symptom reduction ranged from –6% to 26%. Thus, like the hand washing studies, the use of alcohol-based hand sanitizers appears to have a more robust effect on gastrointestinal infections.

Hospital epidemiology noscomial studies

To date, several reviews have examined the database of studies evaluating the evidence of a causal link between hand hygiene and the reduced risk of hospital acquired infections. A recent comprehensive review by Backman *et al.* [30] evaluated 1120 articles on the subject and concluded that "there is a lack of rigorous evidence linking specific hand hygiene interventions with the prevention of health care acquired infections." The conclusion from the Backman review was somewhat different from that of Larson's review [31] but was similar to Silvestri *et al.*'s review [32] concerning the link between hand hygiene interventions and the risk of healthcare acquired infections. However, it is important to note that all three reviews focused on the lack of quality in studies published to date. It is speculated that the nature of the interventions utilized and the diverse factors affecting the acquisition of healthcare-associated infections that complicate the ability to demonstrate an effect of hand hygiene alone.

Safety of handwashes and hand sanitizers

Irritation associated with handwashes and hand sanitizers

A safety concern for both hand washes and hand sanitizers is the occurrence of dermatitis observed in up to 25% of healthcare workers [33]. It is most often attributed to irritation which occurs from repeated contact with detergents and is believed to be exacerbated by the wearing of gloves. A further concern has to do with contact allergies to antibacterial actives and perfumes that are incorporated within the products themselves. Although there are some reports of allergies to these chemistries the accounts of these are limited within the literature [34].

Safety concerns specific to alcohol-based hand sanitizers

In terms of the alcohol-based hand sanitizers, there are occupational safety concerns with the chronic use of alcohol. First is the removal of the lipid barrier of the hands, leading to irritation and an increase in bacterial colonization. Second, the flammability of these alcohol-based formulations has caused some to question whether it is good practice to have them in various locations where the potential for ignition exists. Third are the reports in the literature of intentional ingestion of the alcohol-based products by those individuals with alcoholism and the accidental ingestion by children [35]. Lastly, a safety issue that has called alcohol-based systems into question is the misuse of these products for the prevention of infections. For example, use of alcohol-based hand sanitizers for prevention of infections by norovirus or *C. difficile* is not prudent because it is well established that alcohol has limited efficacy against these pathogens [36,37].

Microbial resistance to antimicrobial agents

The major question concerning antimicrobial-containing hand washes and their use in consumer products has to do with the potential for the development of pathogen resistance [38]. The resistance issue has been divided into two questions:

1 Will the use of these agents in broad scale consumer use result in the loss of their effectiveness?

2 Will the use of these agents lead to cross-resistance to antibiotics?

The majority of the work has been done with triclosan, which has been utilized as an antibacterial agent in several consumer products for 30 years. Triclosan is broad-spectrum antibacterial and antifungal agent. It is more potent against Gram-positive (e.g. *S. aureus*) than Gram-negative bacteria. Triclosan is utilized for therapeutic baths of MRSA-infected patients [39] and in the control of MRSA carriage and skin infections [40]. Unlike orally ingested antibiotics, triclosan elicits bactericidal actions against a variety of bacterial targets reducing the potential for resistance development.

Laboratory observations

Chronic sublethal exposure of laboratory strains of *E. coli* to triclosan selected clones with reduced susceptibility [41].

Although these clones were less susceptible, they were still inhibited by in-use triclosan concentrations. Further studies demonstrated that these observations were limited only to laboratory strains of *E. coli* and in some cases the effects observed with triclosan could be reproduced with a variety of non-antimicrobial materials such as mustard, chili, and garlic [42,43].

Lambert [44] evaluated 256 clinical isolates of *P. aeruginosa* and *S. aureus* over a 10-year period. There was no difference in triclosan sensitivity between antibiotic sensitive and resistant strains. The authors concluded that there was a negative correlation between antibiotics and biocides. Suller and Russell [45] used clinical isolates of *S. aureus* (MSSA and MRSA) to demonstrate no correlation between MRSA and decreased triclosan susceptibility. Furthermore, continuous exposure of a triclosan-sensitive *S. aureus* strain to subinhibitory triclosan concentrations for 1 month did not decrease susceptibility either to triclosan or to other antibiotics.

Antibacterial exposure results from long-term studies

Studies examining exposure to triclosan for 6 months of mixed microbial communities derived from natural environments [46] resulted in no change in triclosan or antibiotic sensitivities.

Cole *et al.* [47] studied 60 homes, 30 of which used antibacterial products and 30 did not. A total of 1238 bacteria were evaluated, with more target bacteria being recovered from biocide users versus non-users. No methicillin, oxacillin, or vancomycin resistant *S. aureus* were isolated associated with the use of biocides. In fact, the incidence of resistance to antibacterials was higher in non-user households. Aiello *et al.* [48] conducted a large (224 households), 12-month study addressing the impact of antibacterial products in homes. Logistic regression analysis demonstrated that the use of biocide products did not result in significant increases in antimicrobial drug resistance nor did it impact susceptibility to triclosan.

Thus, following a comprehensive review of the scientific literature, it is concluded that there is no evidence to support that use of triclosan in consumer products will reduce effectiveness nor contribute to the societal burden of antibiotic resistance. In fact, several accounts in the literature document the utility of triclosan in the reduction of antibiotic-resistant microorganisms including MRSA.

Formulations of hand sanitizers and hand washes

Hand sanitizers can be categorized into three main classes:

1 Alcohol-based = ≥62% alcohol;

2 Alcohol-based supplemented = ≥62% alcohol plus antimicrobial agent;

3 Non-alcohol-based = the majority of the product is water plus surfactant and antimicrobial agent.

In terms of product forms, they span from liquids to gels and foams. Most base efficacy on the fact that they are leave-on products. With the exception of the alcohol-based products that only deliver an immediate benefit and provide no residual activity, hand sanitizers provide both immediate plus a residual antimicrobial benefit.

The antimicrobial hand washes are primarily water-based formulations that are composed of mixtures of surfactants, antimicrobial actives perfumes, and, in some cases, emollients. In many cases, these emollients and skin feel agents are added to improve the consumer experience with the hope of improving the overall compliance. In the USA, antimicrobial actives that can be incorporated within these products are regulated under the TFM. The ingredients are classified into three categories:

1 *Category 1.* Ingredients determined to be safe and effective;

2 *Category 2.* Ingredients determined to be neither safe nor effective;

3 *Category 3.* Ingredients for which there is insufficient evidence; however, the FDA is not objecting to marketing or sale of these products.

Only active ingredients in categories 1 and 3 are allowed to be lawfully marketed in products within the USA.

The formulating of non-alcohol-based hand sanitizers as well as antimicrobial hand washes must take into consideration the bioavailability of the antimicrobial active. For example, some of the surfactants within the formulation may complex or otherwise inactivate the formulation. Recent data with triclosan-containing formulations have demonstrated a difference in efficacy among various triclosan-containing hand washes [49] with varying formulations.

Future directions

It is imperative for our future understanding of this area that improved epidemiologic studies be conducted with a variety of hand hygiene products to better demonstrate the role of hand hygiene for the prevention of infections both in the hospital as well as in the community setting. Additionally, complete hand hygiene strategies must be developed including product efficacy, skin feel, compliance, as well as education. Furthermore, hand hygiene must be examined to assure consumers that both residual as well as immediate germ removal is accomplished. Technologies need to be developed that address consumer as well as healthcare workers' behavior and occupational needs. These technologies must be easy to use and provide the skin conditioning needs for consumers and be effective against a variety of pathogenic bacteria and viruses.

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Chapter 15: Shampoos for normal scalp hygiene and dandruff

James R. Schwartz, Marcela Valenzuela, and Sanjeev Midha
Procter & Gamble Beauty Science, Cincinnati, OH, USA

BASIC CONCEPTS

- Frequent scalp cleansing is important to prevent formation of unhealthy scalp.
- Three classes of shampoos can be delineated: (1) cosmetic shampoos and two types of therapeutic products, (2) standard, and (3) cosmetically optimized therapeutics.
- Both therapeutic scalp care shampoos are effective for normal scalp to prevent unhealthy conditions and for dandruff/seborrheic dermatitis scalp to treat the condition and subsequently prevent its reoccurrence.
- All therapeutic shampoos are not equally efficacious, even though they may contain the same active.
- Cosmetically optimized therapeutic shampoos are desirable as they increase compliance long term because of having no esthetic trade-offs and their affordability.
- All shampoos, including cosmetics, must be mild to the skin while being effective cleansers to minimize irritation that could initiate scalp problems.

Introduction

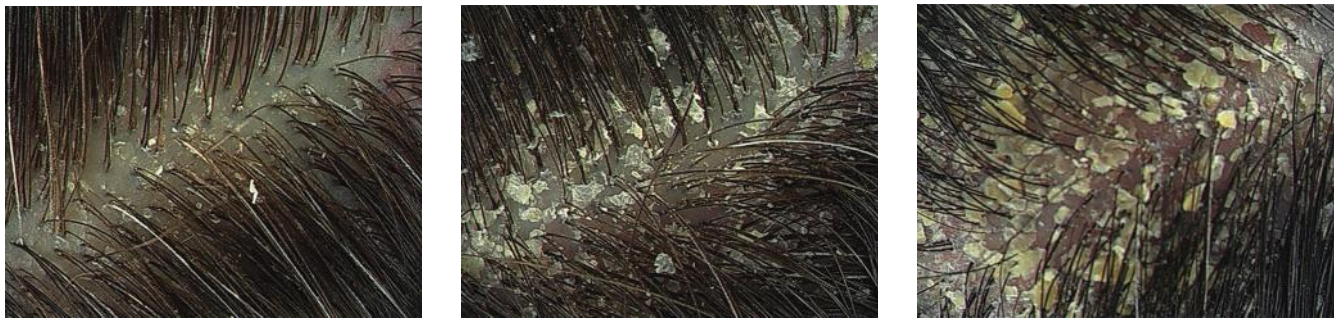
The scalp is a unique environment of the skin combining a high level of sebaceous lipid production with a physical covering of hair. The hair physically protects the scalp from UV light but also can inhibit the cleansing efficiency of the scalp surface by shampoos. These conditions allow for the colonization of commensal *Malassezia* yeasts which can, under the right conditions, cause inflammation and hyperproliferation [1] leading to symptoms [2] of flakes and itch (Figure 15.1). Lipases are secreted by the yeast into the surrounding medium to cause liberation of fatty acids from the triglycerides of the sebaceous lipids. *Malassezia* selectively consume long chain saturated fatty acids to live, the unsaturated fatty acids left behind can then be the initiators of inflammation. Cutaneous inflammation results in hyperproliferation in the epidermis leading to immature stratum corneum cells with incompletely degraded adhesive function resulting in removal as visible clumps.

The resultant condition is called dandruff or seborrheic dermatitis (D/SD), depending on the severity of flaking and the presence of outward manifestations of inflammation. The presence of the condition places special requirements on effective scalp cleansing and it has been observed that scalp issues such as D/SD occur more frequently when cleansing frequency decreases [3]. Because the sebaceous lipids are one of the key factors required for formation of D/SD, infrequent removal leads to the build up of the pro-inflammatory by-products of *Malassezia* metabolism.

Product and formulation technology overview

Three categories of shampoos can be delineated (Figure 15.2). Cosmetic shampoos are primarily designed to cleanse the hair, but of course the scalp skin is cleansed simultaneously. Modern versions of these shampoos also condition the hair by depositing certain ingredients on the hair to improve cosmetic benefits such as ease of combing, shine maintenance, and other attributes important to all consumers. Therapeutic scalp care shampoos (often termed "antidandruff") contain active ingredients to control the D/SD conditions, most often by reducing the *Malassezia* population on the scalp. Standard therapeutic products tend to focus on the drug active without full consideration of product esthetics. Cosmetically optimized therapeutic products also contain a drug active to achieve therapeutic benefits, but without the common esthetic trade-offs of therapeutic products. Recommendations involving therapeutic products must take into consideration that patients also have basic hair care needs and that if the product has significant negative esthetic trade-offs, compliance will be very poor thereby limiting therapeutic efficacy.

Cosmetic Dermatology: Products and Procedures. Edited by Z.D. Draelos.



(a) (b) (c)

Figure 15.1 (a) Image of normal scalp skin. (b) Dandruff scalp image showing adherent white flakes. (c) Seborrheic dermatitis with more evidence of sebum yellowing on flakes and underlying erythema.

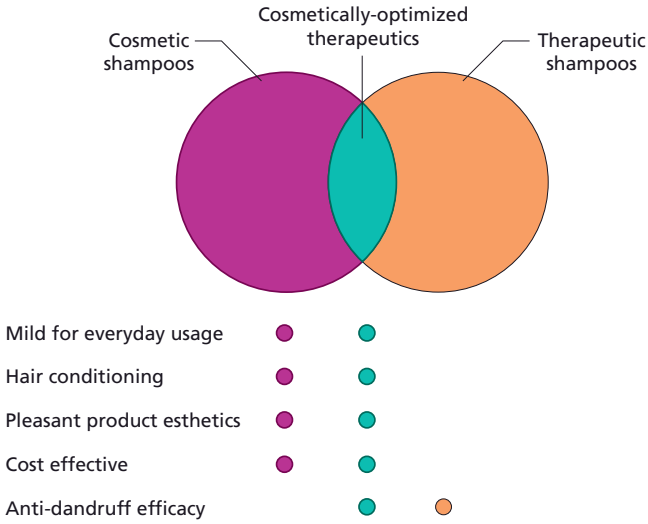


Figure 15.2 Representation of the shampoo segments, differentiating cosmetic from therapeutic shampoos and their key attributes. The category of cosmetically optimized therapeutics achieves therapeutic benefits without diminishing esthetic attributes.

The primary component of all shampoos is surfactants which help to remove sebaceous lipids, keratin debris, particulates from the air, and residues from styling products (Table 15.1). These materials are responsible for the lathering action of a product; the volume of lather is important in the user's perception of cleaning activity. Most of the surfactants tend to be negatively charged (anionic), although some contain both positive and negative charges in the same molecule (amphoteric), and some are uncharged (nonionic); these latter types are considered co-surfactants and function to optimize the lather quality and amount and cleaning ability of the primary anionic surfactant.

The surfactant system is optimized to achieve two opposing objectives – cleaning while minimizing irritation of the skin. All surfactants have the potential to irritate the skin to various degrees. The goal of the formulator is to achieve effective cleaning and lathering while minimizing the irritation potential of the product by using the right surfactants. The addition of co-surfactants can synergistically decrease irritation potential without harming cleaning. Some anti-dandruff actives also can minimize the irritation potential of surfactants (see below); this is especially important for treatment of the D/SD condition which can be exacerbated by an irritating surfactant system.

In addition to surfactants for cleaning, shampoos contain a wide range of other materials to care for the hair and scalp, deliver cosmetic benefits, enhance the usage experience, and to maintain the physical integrity of the product itself (e.g. preservatives, viscosity adjusters, pH control). Hair conditioning agents result in shiny, manageable hair and include such materials as silicones, cationic (positively charged) polymers that show enhanced deposition on the hair fiber to reduce static electricity, humectants to maintain hydration, and materials that penetrate the hair shaft to maintain a healthy-looking appearance.

The cationic polymers mentioned as conditioning aids are also a critical component of the delivery system of many shampoos. While shampoos are first and foremost designed to clean, the achievement of additional hair and scalp benefits requires selected materials to be left behind after rinsing to deliver these benefits. The combination of oppositely charged surfactants and polymers results in an electrostatic association complex called coacervate which forms upon product use and rinsing. The coacervate is an aqueous gel that aids in the delivery of hair and scalp benefit agents to their respective surfaces.

The manipulation of surfactant and polymer types affects deposition efficiency, and together with the type and level of hair benefit agent(s), affects how much conditioning is delivered to the hair. This is the basis for a wide offering of shampoo versions, to meet the diverse hair and scalp needs of users to deliver cosmetic benefits and a pleasant in-use experience, especially in terms of how much hair conditioning is needed and desired. Standard therapeutic shampoos

Table 15.1 Summary of common formulation components of various shampoo types.

Function(s)		Material class(es)	Common examples	Presence in		
				Cosmetic shampoo	Cosmetically optimized therapeutic	Standard therapeutic shampoo
Lather/cleaning		Primary surfactants	Sodium lauryl sulfate, ammonium lauryl sulfate, sodium laureth sulfate, ammonium laureth sulfate	Yes	Yes	Yes
	Optimization	Co-surfactants	Cocamidopropyl betaine, Cocamide MEA	Yes	Yes	Yes
Hair conditioning agents	Shine, manageability	Silicones	Dimethicone, dimethiconol, amodimethicone	Yes	Yes	
	Detangling, Antistatic	Cationic polymers	Polyquaternium-10, cationic guar derivatives	Yes	Yes	
	Hydration	Humectants	Glycerin, urea	Some	Some	
	Hair health		Panthenol and derivatives	Some	Some	
Deposition aids	Benefit delivery	Cationic Polymers	Polyquaternium-10, cationic guar derivatives	Yes	Yes	
Preservatives		Biocides	Isothiazalinone derivatives, parabens	Yes	Yes	Yes
Fragrance				Yes	Yes	Yes
Thickeners	Viscosity	Salts	Sodium chloride	Yes	Yes	Yes
		Particles	Glycol distearate	Some	Some	Some
Antidandruff components	Scalp care	Antifungals	Pyrithione zinc (PTZ), selenium sulfide, ketoconazole (Table 15.2)		Yes	Yes
		Potentiators	Zinc carbonate		Some	

tend to be deficient in hair conditioning benefits. They also do not tend to have a range of versions to meet the esthetic needs of the user. Together these two factors limit compliance with standard therapeutic products.

Therapeutic scalp care shampoos additionally contain active materials for resolving D/SD and preventing its reoccurrence. Because the commensal scalp fungus *Malassezia* clearly has a role in the etiology of the condition [1], the primary function of most scalp care active materials is antifungal; the most common are referred to in Table 15.2, grouped by their intrinsic anti-*Malassezia* potency. Many of the materials are accepted by global regulatory agencies, while some are used in more limited geographic applications.

The most commonly used scalp active is pyrithione zinc (PTZ), a material developed as part of a program to identify biocides based on the naturally occurring antibiotic aspergillic acid [4]. Screening of over 1000 prospective antidandruff materials in the late 1950s led to the selection of PTZ; novel formulation work then led to commercialization of shampoos with PTZ in the early 1960s [5]. Since that time, the efficacy, ease of formulation, cost, and compatibility with esthetic shampoos has resulted in very broad use and acceptance of PTZ and technical developments which continue to improve its therapeutic benefit (see below).

Other effective actives such as ketoconazole and selenium sulfide are used fairly broadly, but tend to be more limited to the standard therapeutic class of shampoos either because of cost, regulatory, or esthetic limitations. Such products are generally used when especially difficult cases of D/SD occur. If such products are needed, subsequently switching to cosmetically optimized therapeutic shampoos should be advised for prophylactic usage. Materials such as climbazole and octopirox have been used regionally, but have been limited by the lack of acceptance by the US Food and Drug

Table 15.2 Overview of scalp care active materials.

Common actives	Primary mechanism	Typical amount used	Physical characteristics		Usage
			Appearance	Odor	
Most potent antifungal activity					
Pyrithione zinc (PTZ)	Antifungal	0.5–2%	White powder	Neutral	Wide. Positive impact on esthetics and hair care benefits
Ketoconazole	Antifungal	1–2%	White powder	Neutral	Limited. Is expensive and requires regulatory approval
Selenium sulfide	Antifungal	1–2%	Red powder	Sulfur-like	Limited. Color and odor affect esthetics
Moderately potent antifungal activity					
Climbazole	Antifungal	0.5–2%	White powder	Neutral	Limited. Not accepted globally by regulatory bodies
Octopirox	Antifungal	0.5–2%	White powder	Neutral	Limited. Not accepted globally by regulatory bodies
Sulfur		1%	Yellow powder	Sulfur	Limited. Color and odor affect esthetics
Least potent antifungal activity					
Salicylic acid	Keratolytic agent	1.8–3.0%	White powder	Neutral	Limited. Low antifungal potency
Coal tar	Regulator of keratinization	0.5–1.0%	Black viscous liquid	Off-odor	Limited. Color and odor affect esthetics

Administration (FDA). Although the FDA does accept the safety and efficacy of salicylic acid, coal tar, and sulfur, either low potency or poor esthetics have limited their broad utilization.

Unique attributes of scalp care products

The complexity of the shampoo delivery vehicle described above in combination with the unique attributes of the active material accounts for varying levels of efficacy obtained when using similar actives at identical levels. The case is well-illustrated for shampoos based on PTZ, in which the physical form of the material as well as the shampoo composition affect resultant activity [1] by three parameters (Table 15.3).

Regardless of the type of active material used in shampoos, activity is derived from how much material is retained on the scalp surface after rinsing. This is a complex formulation technology task because cleaning is occurring simultaneously. The efficiency of the coacervate technology delivery system directly impacts how much of a material such as PTZ is retained on the scalp after rinsing. This efficiency of this deposition can vary dramatically between commercial products and will directly affect efficacy [6]. The achievement of effective active delivery is a complex balancing of parameters to maximize delivery while not compromising the esthetic properties of the product.

Table 15.3 Formulation factors affecting the realization of full efficacy.

1 Retention of active material on scalp after rinsing
2 Physical bioavailability: spatial coverage of active on scalp surface
3 Chemical bioavailability: prevalence of active species of active

While the amount of material remaining on the scalp surface is critically important, the physical distribution and bioavailability of the material is just as important. For a particulate material such as PTZ, there is substantial technology in the optimization of the particle morphology (shape and size) to improve physical distribution on the scalp surface. There are two types of PTZ in use today. Standard PTZ has a submicron size and a nondescript morphologic shape. Optimized PTZ is used by one manufacturer where the morphology is platelet (Figure 15.3) and the particle size has been optimized to 2.5 µm. Both of these parameters are designed to maximize the efficiency of scalp surface cover-

age to achieve uniform benefits throughout the microenvironment of the scalp. This is important as the effective zone around a PTZ particle (Figure 15.4a) is limited by the molecular solubility of PTZ in the surrounding medium of sebaceous oils. By use of platelet morphology particles, the spatial coverage is more efficient than use of a three-dimensionally symmetric particle. Particle size of the platelet is also important to achieve uniformity of coverage. Ideally, smaller particles are better, but they suffer from a trade-off that they are more difficult to retain through the rinsing step. Thus, practically, it has been observed [1] that an optimum particle size is 2.5 μm, which represents the average size of the optimized PTZ material. Together, these attributes constitute physical bioavailability.

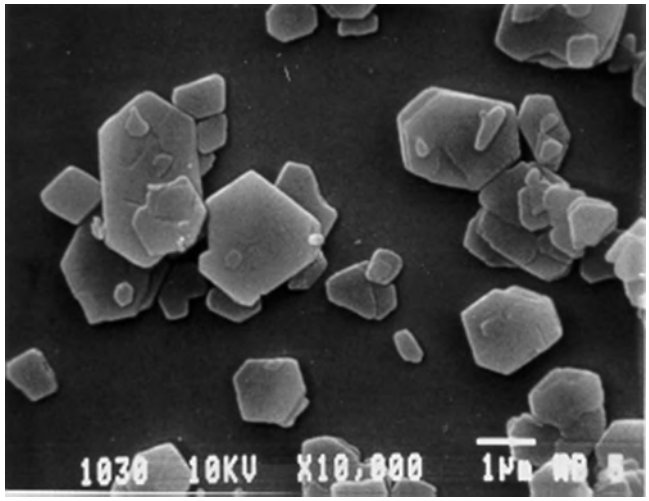
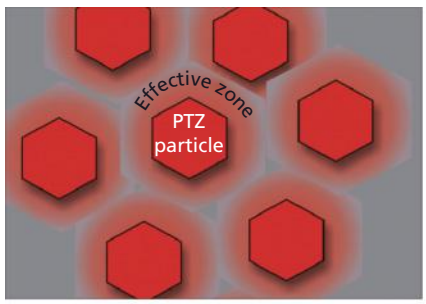


Figure 15.3 Electron micrograph of a unique form of pyrithione zinc (PTZ), optimized for size and morphology to maximize the efficiency of surface coverage.

The third factor affecting delivered efficacy is optimization of chemical bioavailability [7]. Chemically, PTZ is considered a coordination complex between inorganic zinc ion (Zn) and the pyrithione (PT) organic moiety. In such a material, the bonds are weak and an equilibrium exists between the intact species and the separate components (Figure 15.4b). Neither of the separated components (Zn and PT) are effective antifungals; thus, to the extent this dissociation occurs, PTZ chemical bioavailability and resultant efficacy is reduced. By adding a common ion to the system (in the form of zinc carbonate), the equilibrium is shifted (exploiting LeChatelier's principle) to the intact and more effective PTZ; this unique potentiated PTZ formula thus maximizes bioavailability of the deposited material.

Another important aspect in product selection is that the cleaning activity of the shampoo not result in irritation of

(a)



(b)

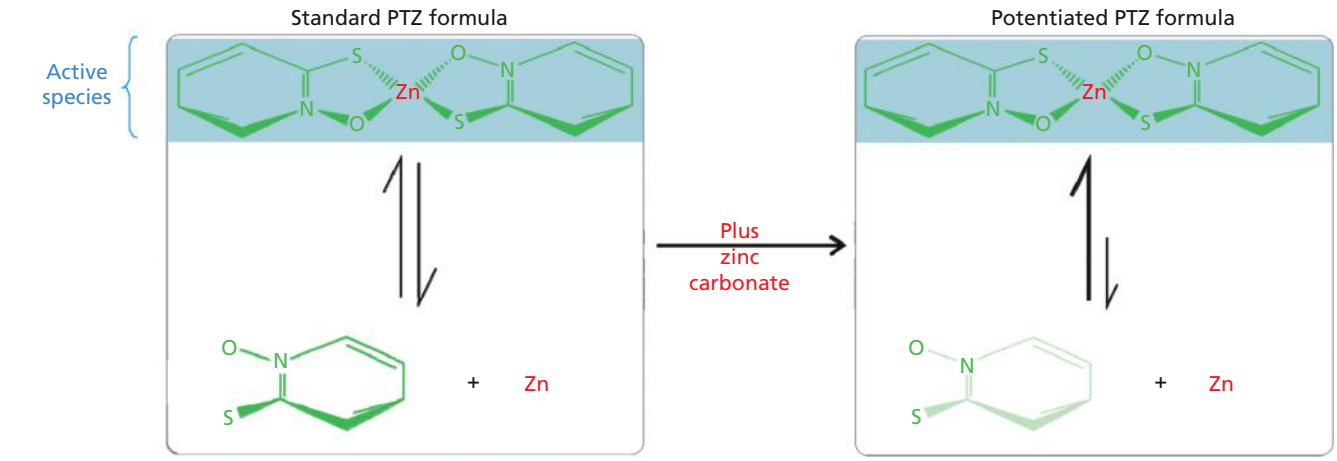


Figure 15.4 (a) Conceptual representation of the zone of inhibition of fungal growth surrounding PTZ particles and the importance of spatial distribution of particles to achieve uniformity of coverage. (b) PTZ can dissociate into component pyrithione (PT) and zinc (Zn) which reduces the presence of the intact bioactive species. The addition of zinc carbonate alters this equilibrium to maintain PTZ in its bioactive intact form.

Table 15.4 Summary of advantages and disadvantages of using scalp care shampoos.

Advantages
Convenient form for treatment and prevention of dandruff/seborrheic dermatitis
For cosmetically optimized therapeutics, compliance is increased
• Affordability
• No esthetic trade-offs
For PTZ-based products, over 50 years of safe utilization
For PTZ-based products, no tachyphylactic responses
Disadvantages
For straight therapeutic products, compliance is reduced
• Can be very expensive
• Can have substantial esthetic trade-offs

Table 15.5 Summary of usage habits to maximize the therapeutic benefit.

1 Use the therapeutic shampoo for *every* shampooing to prevent a relapse
2 Use a therapeutic product that is cosmetically optimized and affordable
3 Shampoo as frequently as possible
4 Lather exposure time is not important but repeating the entire process can be beneficial
5 Product should be utilized all year
6 If a rinse-off conditioner is needed, use one that contains antidandruff active

the scalp. For those with D/DS this would interfere with the natural cutaneous repair processes that occur upon *Malassezia* population reduction. In addition to appropriate selection of the surfactant system as described above, some antifungal actives such as PTZ have been shown to reduce the irritation potential of the surfactants [8].

Advantages and disadvantages

The use of therapeutic shampoos for effective treatment of D/SD as well maintenance of normal scalp hygiene is very convenient because the patient will be utilizing this product in the shower already (Table 15.4). By choice of a cosmetically optimized therapeutic product, the user suffers no esthetic trade-offs (compared to cosmetic shampoos) that would limit compliance. This class also tends to be more affordable than standard therapeutic products, which also increases long-term (prophylactic) usage. No diminution of benefit (e.g. tachyphylaxis) occurs upon long-term use of PTZ-based products; this is based on both designed clinical studies [9] as well as anecdotal evidence associated with over 50 years of usage history. The only disadvantage of using such scalp care products occurs when a strict therapeutic product is chosen. The expense and esthetic negatives that normally accompany such products limit patient compliance leading to frequent frustrating condition reoccurrence; these products should be limited to the most recalcitrant of cases.

Effective use of products

D/SD is a chronic condition characterized by frequent reoccurrence, resulting in frustration on the part of the patient (Table 15.5) [10]. Initial treatment of the condition appears to be managed fairly effectively by either independent use of therapeutic antifungal shampoos or by combination with topical corticosteroid usage. However, preventative treatment is required for long-term management of the condition. Because *Malassezia* easily recolonize, using a cosmetically optimized therapeutic product for each shampoo experience is the optimum method for preventing reoccurrence.

If cosmetic shampoo usage is interspersed with therapeutic products, efficacy is decreased [11]; not only does the cosmetic shampoo not deliver active to the scalp, it washes off any deposited material from the prior exposure to the active-containing shampoo. The desire to switch between a cosmetic shampoo and therapeutic product is either the real or perceived esthetic trade-offs in use of a therapeutic product. It has been shown [12] that therapeutic products do not provide all of the desired esthetic benefits and that this will drive patients to choose cosmetically optimized therapeutic shampoos for treating scalp conditions. Even with cosmetically optimized therapeutic products, there is often a *perception* that these products are not equivalent to cosmetic shampoos. While this may have been true in the past, modern technologies can deliver efficacious therapeutic and cosmetic benefits without the traditional trade-offs of standard therapeutic treatments.

A wide range of D/SD shampoo treatments are available [13], with widely ranging costs. By recommending a therapeutic product that has been cosmetically optimized and one that is affordable for ongoing usage, the patient is best advised to use this product as their normal product to prevent reoccurrence.

Even by selection of an effective therapeutic product, how it is used can make a difference to the magnitude of benefit achieved. The length of time the lather is exposed to the scalp is generally not important as it is the material that is retained on the scalp after rinsing that provides the benefit. Using coacervate-based deposition technologies, it is the rinsing that triggers the deposition. Repeating the lathering and rinsing process twice will more thoroughly remove the sebaceous lipid and allow more active to be deposited.

D/SD symptoms occur year-round and should be treated all year. There is a misperception that it is a seasonal condition, primarily occurring in cold, dry seasons. This has been shown not to be true [11]. Winter months with less humid air combined with the tendency to wear darker clothing make the patient more able to detect the flaking symptoms under these conditions, but they occur all of the time. Higher frequency of shampooing may occur in summer months resulting in a slight decrease in severity of symptoms.

Another critical usage factor involves whether a rinse-off conditioner is used after the shampoo [11]. Rinse-off conditioners that do not contain antidandruff actives remove a portion of the deposited active from the prior therapeutic shampoo exposure thereby reducing efficacy. If the patient desires use of a rinse-off conditioner, one containing antidandruff active should be recommended so that loss of retained active does not occur once the entire hair care regimen is practiced.

Benefits of use of scalp care shampoos

Resolution of D/SD is the primary motivation for initiation of use of therapeutic shampoos. The choice of shampoo should be motivated by, in order: efficacy, cosmetic hair benefits, and cost. Assessing the relative efficacy of a product usually involves double-blind placebo-controlled drug studies using medical experts to grade the severity of flaking and erythema. A review of the comparative efficacy of products [3] supports that the most effective products are those that contain an effective antifungal, the most potent of which are PTZ, selenium sulfide, and ketoconazole. Further rank-ordering within this group is somewhat difficult because of conflicting studies and the part that the specific formulation then plays. However, it is clear that cosmetically optimized therapeutics can be as effective as standard therapeutics; the marketing strategy used to position these products is not necessarily a good predictor of the true technical efficacy.

The use of certain scalp care shampoos also demonstrate the ability to deliver anti-irritancy effects [14]. There appears to be a wide range in activities depending on the specific active used. PTZ, and especially the potentiated PTZ formula, appears to be most effective at reducing irritation. Irritation and inflammation are early steps in the etiology of D/SD as well as many other scalp conditions. Thus, use of the zinc-based therapeutic products may well have general scalp health benefits beyond D/SD mitigation [15].

The scalp health benefits associated with use of antidandruff shampoos may extend to hair benefits as well. A number of studies have demonstrated (e.g. Berger *et al.* [16]) that use of these products can reduce the rate at which hair is lost. The mechanism for this benefit is not known, but may be speculated to originate in the reduction of inflammation referred to above as follicular inflammation may impede regrowth of lost hairs. A further benefit of the scalp inflammation being reduced by these products is less itch and subsequent scratching which reduces hair damage and improves the quality and appearance of hair.

Conclusions

Normal scalp hygiene requires frequent and effective cleaning of the scalp. Cosmetic shampoos do this effectively while providing conditioning benefits for the hair. For many individuals, this frequent cleaning is sufficient to prevent adverse scalp effects. However, many still experience the symptoms of D/SD. For this group, therapeutic products are required that contain antidandruff actives that control the scalp *Malassezia* population. A subset of this class is cosmetically optimized therapeutics in which the product delivers the therapeutic benfits without loss of the typical cosmetic shampoo esthetics. This leads to much higher compliance, leading to effective long-term care of the chronic condition. Other factors relevant for selecting the most useful product are that the active and shampoo composition be optimized to maximize the physical and chemical bioavailability of the active; this is especially true for PTZ-based treatments. Once the best shampoo is chosen, effective habits are required to realize the full benefit: frequent use without switching to cosmetic shampoos, use all year around, and the use of a rinse-off conditioner that also contains antidandruff active.

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Part 2: Moisturizers

Chapter 16: Facial moisturizers

Yohini Appa
Johnson & Johnson, New Brunswick, NJ, USA

BASIC CONCEPTS

- Facial moisturizers can be used to improve skin texture, treat dry skin, and provide sun protection.
- Occlusives, humectants, emollients, and sunscreens are important ingredient categories in facial moisturizers.
- The efficacy of a facial moisturizer can be measured via transepidermal water loss and corneometry.
- Facial moisturizers can be an important adjunct in the treatment of facial dermatoses, such as atopic dermatitis and eczema.

Introduction

The face is the most conspicuous representation of age and health. While the eyes are considered the windows to the soul, the face is its billboard. No other body part demonstrates personal past history as convincingly as the face. Wrinkles form on the face well before the rest of the body and serve as an indicator of age and lifestyle. The relative color and luminosity of the facial skin represents overall health and emotional state. Facial skin can be dull to vibrant representing poor to excellent physical health. The face mirrors acute changes in well-being. For example, persons experiencing cardiac distress appear "ashen" while anger or embarrassment may be expressed as a reddened face. Thus, the face represents the current physical state of the individual. Moisturizers can enhance the appearance of the face and are thus important cosmeceuticals.

The face is rarely covered and constantly subjected to the elements. It is one of the most light-exposed areas of skin on the body, the other areas being the shoulders, upper chest, and forearms; as a result it receives high amounts of UV radiation. The incidence of cutaneous melanoma as measured by relative tumor density is highest on the face in subjects over the age of 50 years, a statistic that is interpreted as directly correlating to the amount of long-term UV exposure [1]. This means that facial photoprotection is of great importance, thus the incorporation of efficacious UVA and UVB protection in daily facial moisturizers is worthwhile.

Cosmetic Dermatology: Products and Procedures. Edited by Z.D. Draelos.

Facial skin is physiologically unique. It possesses numerous sweat glands and a relatively thin dermis. It is densely populated with sebaceous glands, possessing 400–900 glands per square centimeter [2]. The face is a major point of contact for sensory input, the facial skin possesses high innervation and is therefore more sensitive than skin elsewhere on the body [3]. The skin covering the face also has to allow for the subtleties of facial expressions and phonoation. Of all the areas on the body, the skin on the face has the highest level of hydration. When the ratio of transepidermal water loss (TEWL) to skin surface hydration was calculated in order to determine the most consistently hydrated area of the body, the forehead and cheek showed the lowest ratios (Figure 16.1).

Dry facial skin

Dry skin is a term used to describe the condition that arises when the normal functioning of the skin is compromised. More specifically, it is a manifestation of the consequences that arise from a loss of water from the outermost layer of the dermis: the stratus corneum (SC). The SC is formed when keratinocytes, cuboidal cells in the lower half of the epidermis, migrate from the basal layer to the most superficial layer, producing large amounts of the water-insoluble protein keratin along the way. The keratinization and migration process results in flattened, keratin-filled keratinocytes, referred to as corneocytes, which create an overlapping barrier with a "brick and mortar" appearance that is nearly waterproof. The gaps between the corneocytes, or "bricks," are filled with intercellular lipids, or "mortar" that is produced by keratohyaline granules. The SC layer is also

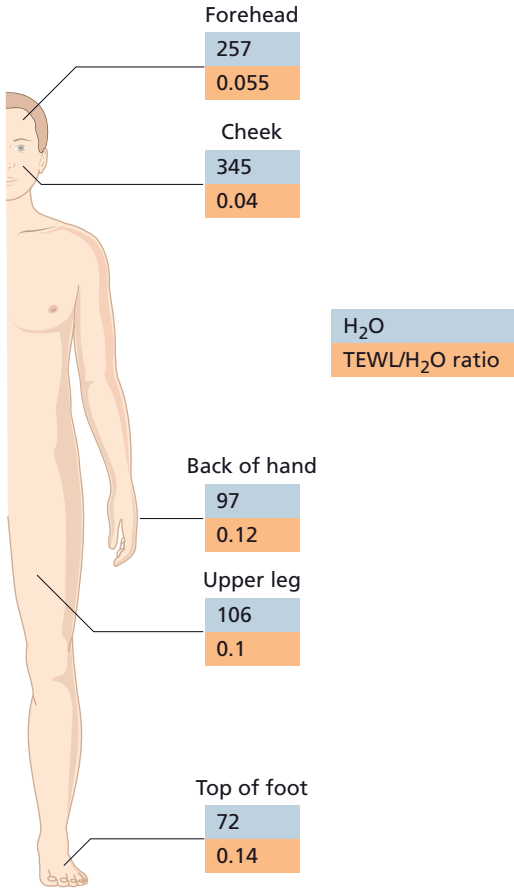

Figure 16.1 Skin surface hydration and transepidermal water loss (TEWL) and SciCon ratio.

referred to as the "dead layer" because by this point the cells have stopped synthesizing proteins and are unresponsive to cellular signaling. Cells in the SC are eventually sloughed off and replaced by more cells coming up through the epidermis, thereby maintaining a continuous barrier. It normally takes 26–42 days for the epidermis to cycle completely [4].

The process of skin cell differentiation and maturation is a delicate balance that is easily disrupted. If the water content of the SC drops below 20% for an extended period of time, the enzymes involved in desquamation will be unable to function and the process of orderly epidermis cycling will be compromised. This especially apparent in dry facial skin.

There are many functions that the epidermal barrier performs:

1 Maintains a 20–35% water content;
2 Limits TEWL;
3 Preserve water homeostasis in the epidermis;
4 Sustains optimal lipid synthesis; and
5 Allows for orderly desquamation of SC cells.

A shift away from equilibrium in one of these five functions can result in a compromise of the barrier and the basic consequence is what we refer to as "dry skin." More specifically, when TEWL is increased to the point that the water content in the SC is reduced to below 10%, the clinical signs of xerosis will appear [5].

The orderly desquamation of the SC is a complex process which if disturbed can lead to a self-renewing cycle of dry skin. The corneocytes that make up the SC are highly interconnected and able to withstand a large amount of mechanical stress. When new cells are formed, enzymatic digestion of the proteins anchoring the old cells is required for removal. The level of humidity in the SC is a critical factor modulating the activity of these desquamatory enzymes, specifically stratum corneum chymotryptic enzyme (SCCE). When this process breaks down, desquamation becomes irregular and dead SC cells slough off in large clumps; representing the "flaking" seen in so many dry facial skin conditions [6].

The sebum-rich skin of the face can appear moisturized but possess a low water content. Sensory symptoms can include but are not limited to: dryness, discomfort, pain, itching, stinging, or tingling sensations. Tactile signs are rough, uneven, and sand-like feeling skin. Visible signs, which can be macroscopic or microscopic, are redness, dull surface, dry white patches, flaky appearance, and cracks and fissures. There are many causes for these signs and symptoms. In all, the presence of dry skin represents disorder in the complex system that continually renews the facial skin.

Facial moisturization

The physiologic goal of facial moisturization is to restore the elasticity and flexibility of the SC, thereby restoring its barrier function. Additionally, the reintroduction of humidity to the SC allows for proper functioning of desquamation enzymes and restores the natural skin renewal cycle. Kligman and Leyden [7] defined a moisturizer as "a topically applied substance or product that overcomes the signs and symptoms of dry skin." The esthetic goal of moisturization is achieving soft, supple, glowing, healthy looking skin, as subjectively evaluated by the end-user. Regular use of facial moisturizers mitigate and prevent signs of aging, especially when formulated with broad-spectrum sun protection for daytime use.

Because the face is one of the most sensitive areas of the body, a facial moisturizer must meet esthetic goals in addition to fulfilling a broad set of performance attributes. Consumers expect a facial moisturizer to reduce dryness, improve dull appearance, smooth and soften the skin, and increase suppleness [8]. Furthermore, these expectations

Table 16.1 Function of common moisturizer ingredients. This listing represents the common ingredients found in a moisturizer formulation identifying the role of each of the substances in the ingredient disclosure.

	Humectant	Emollient	Occlusive	Emulsifier	Preservative
Dimethicone		X	X		
Trisiloxane		X			
Glycerin	X	X			
Glyceryl stearate				X	
PEG 100 stearate				X	
Potassium cetyl phosphate				X	
Behenyl alcohol			X		
Caprylyl methicone		X			
Hydrogenated palm glycerides		X			
Hexanediol	X	X			
Caprylyl glycol	X	X			
Cetearyl glucoside			X		
Cetearyl alcohol			X		
Methylparaben					X
Propylparaben					X
Methylisothiazolinone					X

must be achieved by a moisturizer with a minimal presence and pleasant sensory qualities.

A properly formulated moisturizer can supplement the function of the endogenous epidermal lipids and restore the epidermal barrier function. This allows the skin to continue its natural process of renewal and desquamation at a normal rate. The substances utilized by all moisturizers to achieve this desired effect fall into a handful of basic categories (Table 16.1). Humectants, such as glycerin, attract and hold moisture, facilitating hydration. Emollients, typically lipids or oils, enhance the flexibility and smoothness of the skin and provide a secondary soothing effect to the skin and mucous membranes. Occlusives create a hydrophobic barrier to reduce water loss from the skin. Emulsifiers work to bring together immiscible substances; they are a critical element in the oil and water mixtures employed in moisturizer formulas. Preservatives prevent the premature breakdown of components and inhibit microbiologic growth. Fragrances not only add to the esthetic value but can also mask the odor of formulation ingredients.

These components make up the basic formulation of any moisturizer, and the choices available to achieve the preferred outcome are vast. The formulation of an acceptable and effective moisturizer for the face, one that will enable the natural processes of skin desquamation to occur and maintain healthy barrier function while meeting high esthetic standards, is as much an art as it is a science.

Facial moisturizer formulation

Facial moisturizers are typically oil-in-water emulsions. The water improves skin feel and offers an acceptable, universally tolerated base for the active ingredients. The water or oil solubility of components is inconsequential because both are present. Emulsions allow for a wide range of properties, such as slow to fast absorption rates depending on the final viscosity of the formulation. The fine-tuning of these properties is important for achieving the high esthetic expectations of a facial moisturizer. For example, a daily-use formula with high emollient content may feel heavy in a cream but be acceptable in liquid form. Conversely, overnight creams with antiaging additives may be thick in order to remain on the face during sleep and to slow the absorption of active components. Therefore, by utilizing a range of water to oil ratios, and varying humectant and emollient mixtures, the desired effects can be formulated within the acceptable esthetic parameters for a facial moisturizer.

Moisturizer ingredients and function

Humectants

The overall hydration level of the SC affects its mechanical properties. If the water level in the SC drops below 10%, its flexibility can be compromised and it becomes susceptible to damage from mechanical stress [9]. Humectants are key substances to maintain skin hydration. Natural humectants, such as hyaluronic acid, are found in the dermis, but external humectants can be externally applied in moisturizers. Humectants draw water from the viable epidermis and dermis, but can draw water from the environment if the ambient humidity is over 80%.

Humectants are water-soluble organic compounds that can sequester large numbers of water molecules. Glycerin, sorbitol, urea, and sodium lactate are all examples of externally applied humectants. Glycerin, also referred to as glycerol, is one of the most widely utilized compounds in cosmetic formulations because of its effects on multiple targets and its universal applications. Its chemical structure brings together the stability of three carbon atoms with three water-seeking oxygen atoms in an anisotropic molecule that is perfectly designed for use in skin and hair moisturizers. Glycerin also allows for the construction of different product physical forms that cover the spectrum from sticks to microemulsions to free-flowing creams that maintain stability over time.

The degree of purity to which glycerin can be manufactured not only ensures consistency and facilitates microbiologic stability, but also guarantees the minimization of allergic reactions by contaminants. The pure form of glycerin has been tested on thousands of patients and millions more have used it with extremely few reports of ill effects. Glycerin is generally classified as a humectant; however, this characteristic is not the sole reason for its ability to achieve skin moisturization, in fact, it performs a number of different functions that are not directly related to its water-holding properties.

Glycerin can restore the suppleness of skin without increasing its water content, a trait that is exploited by its use in the cryopreservation of skin, tissue, and red blood cells, where water would freeze and damage them. Glycerin enhances the cohesiveness of the intercellular lipids when delivered from high glycerin therapeutic formulations, thereby retaining their presence and function. Furthermore, glycerin has been identified as a contributor to the process of desquamation, a critical component of the dermal renewal cycle, through its ability to enhance desmosome digestion.

In addition to its direct, humectant effects on skin moisturization, endogenously produced glycerin has exhibited effects at the molecular level in knockout mouse model studies, confirming its role in maintaining SC hydration and barrier maintenance. A recent study showed that glycerin content was three times lower, SC hydration was reduced, and barrier function was impaired in mice deficient in the water/glycerin transporter protein, aquaporin-3 (AQP3) despite normal SC structure, protein–lipid composition and ion–osmolyte content. Glycerin, but not other small poly glycols, restored normal SC moisturization and TEWL values when applied to the AQP3-deficient mice, confirming that glycerin was physiologically necessary in the modulation of SC hydration and barrier maintenance [10].

Glycerin remains the gold standard for moisturization. The fact that it acts on so many different parameters with a nearly non-existent side-effect profile makes it a prime candidate for facial moisturizer formulations. It is also an excellent example of how moisturizer components, especially those used on the face, should be considered for their ability to enhance and protect the skin. Glycerin raises the bar for moisturizers in that it is capable of enhancing, or even rescuing, the intrinsic processes that are in place to maintain the orderly maturation of keratinocytes and the barrier function of the skin.

Occlusives

Humectants are only partially effective in moisturizing the skin. In order to maintain epidermal water content and preserve the barrier function of the SC, occlusive agents are employed in a role meant to complement the water-attracting nature of humectants. Occlusive agents inhibit evaporative water loss by forming a hydrophobic barrier over the SC and its interstitial areas. Occlusion is successful in the treatment of dry skin because the movement of water from the lower dermis to the outer dermis is a guaranteed source of physiologically available water. Moreover, these occlusive agents have an emollient effect, as is the case with behenyl alcohol.

Petrolatum and lanolin are two historically popular occlusives that are slowly being replaced by more sophisticated alternatives. Petrolatum is a highly effective occlusive, but it suffers from an unfavorable esthetic. Lanolin is not recommended for use in facial formulations because of its odor and potential allergenicity [11]. Newly constructed silicone derivatives have been employed in moisturizers for their occlusive properties, and they further enhance the esthetic quality of the formulation by imparting a “dry” touch. This technologic advancement is also an example of how the esthetic parameter of a facial moisturizer can have a major effect on compliance and willingness to apply.

Emollients

Emollients are agents, usually lipids and oils, designed to soften and smooth the skin. Lipids are non-polar molecules and as such they repel polarized water molecules, thereby limiting the passage of water to the environment. The most prevalent lipids in the SC, especially within the extracellular membranes, are ceramides. They comprise about 40% of the lipid content of the SC, the remainder of which is 25%

cholesterol, 10–15% free fatty acids, and smaller quantities of triglycerides, stearyl esters, and cholesterol sulfate. These lipids are synthesized throughout the epidermis, packaged in lamellar granules, and eventually differentiate into multilamellar sheets that form the ceramide-rich SC water barrier [12].

The purpose of an emollient is to replace the absent natural skin lipids in the space between the corneocytes in the SC. Additional benefits include the smoothing of roughened skin thereby changing the skin's appearance, and providing occlusion to attenuate TEWL and enhance moisturization. Of the three components of skin moisturizers listed in the CTFA Cosmetic Ingredients Directory, emollients outnumber occlusives 2 to 1 and the humectants 10 to 1. This is an indication not only of the number of available compounds that can perform this function, but also the variety of lipids that can be utilized [13].

Fragrance

Fragrance is a component of facial moisturizers that is often dismissed as an unnecessary potential irritant, but this idea is becoming increasingly antiquated as the science supporting its proper use and evaluation is improved. Vigorous protocols have been developed that comprehensively and conclusively assess the tolerance of formulations on human subjects. Fragrances are screened separately first and then together in both normal and sensitive populations, and utilized at the minimum concentration required to mask the smell of certain components, if necessary. Fragrance improves the overall esthetic qualities of the moisturizer, which is an important component of any moisturizer formulation, especially one that is applied to the face.

Preservatives

Preservatives are also subject to the same rigorous testing protocols as fragrances. The preservative must be strong enough to completely inhibit bacterial growth, but must not be sensitizing or irritating. Preservatives are an important component in facial moisturizers to prevent the lipids in the formulation from becoming rancid. All facial moisturizers have some type of preservative, because there is really no such thing as a preservative-free formulation.

Photoprotection and facial moisturizers

Sunscreens could be considered to be the most globally effective ingredient added to a facial moisturizer. Because the incidence and mortality rates of skin cancer have been steadily rising in the USA, the use of sunscreen as a daily protectant has become more important to consumers. There are both immediate and long-term benefits from photoprotection. The immediate benefit is the prevention of a painful sunburn while long photoprotection results in reduced photodamage manifesting as wrinkling, inflammation, and dryness.

A key immediate event that leads to chronic photoaging is the production of proteases in response to UV irradiation at doses well below those that cause skin reddening. Matrix metalloproteinases (MMPs), for example, are zinc-dependent endopeptidases expressed in many different cell types and are critical for normal biologic processes. They may also be involved in desquamation processes, and overexpression would lead to early sloughing and increase in TEWL. With a proper sunscreen regimen, production of MMPs is minimized and their participation in chronic photoaging can be avoided. The addition of sunscreens to facial moisturizers also contributes to the prevention of reactive oxygen species (ROS) production, Langerhans cell depletion, and sensitivity to UV radiation, as is observed in polymorphous light eruption.

Facial moisturizer testing

The formulation of a moisturizer centers on the primary goal of delivering the perception of moisture to the skin. This includes not only adding moisture to the skin, but also the improvement of the barrier function and reinstating natural skin reparative processes. The testing of the efficacy of a moisturizer is based on barrier function assessment.

There are many ways to assess the barrier function of the skin based on SC integrity. Measurement of the TEWL is one method. A damaged SC allows water to evaporate resulting in high TEWL readings. These measurements are taken with an evaporimeter, which measures the amount of water vapor leaving the skin. The amount of water in the skin can also be measured via skin conductance. This technique, known as corneometry, measures the amount of low level electricity conducted by the skin. Because water is the conductor of electricity in the skin, the amount of current conducted is directly related to the water content. Thus, the efficacy of a moisturizer can be measured by its effect on water vapor loss and skin conductance.

Another method for evaluating skin dryness is D-squames. D-squames are circular, adhesive discs placed on the skin surface with firm pressure and then pulled away. The removed skin is observed and parameters such as the amount of skin removed, size of flakes, and coloration can be recorded. Differences between dry skin and normal moisturized skin are clearly evident upon examination of the disc, and further characterization can be carried out to differentiate levels of dryness and qualitative differences in desquamation.

The barrier function of the skin can be assessed following application of an irritant to the skin surface. The introduction of an irritant can cause erythema and scaling in the compromised SC. A frequent irritant used for the assessment of barrier function is sodium lauryl sulfate (SLS). The amount of erythema and TEWL is measured following

scrubbing of the skin with SLS. Skin with a better barrier following use of an efficacious moisturizer will experience less damage than skin that possesses a compromised barrier.

Finally, after testing the efficacy of the formulation in a controlled, laboratory setting, its efficacy must be evaluated on a group of consumers. Consumer testing is usually carried out in a blind study involving 200–300 subjects, from geographically disparate locales in order to normalize any differences in skin types or backgrounds. This testing will introduce parameters that are evaluated subjectively by the population of subjects such as skin feel, perception of texture, ease of application, and scent, among other things, that define its esthetic qualities. The functional qualities of the moisturizer, such as "immediate comfort" and "long-lasting effect" will also be evaluated by the consumer group and incorporated into the overall assessment.

Use of facial moisturizers in common inflammatory dermatoses

The face presents a set of unique challenges regarding the treatment of skin disorders. What may be acceptable for treatment regimens elsewhere on the body, such as a strong occlusive such as petrolatum or a humectant such as urea, will be esthetically challenging to the user and stand in the way of compliance. While it is easy to think of esthetics as secondary to efficacy of treatment, it should be considered of primary importance where the face is concerned. This concept cannot be overstressed because the sensitivity of the facial skin to the sensory and olfactory qualities of moisturizers is much higher than the rest of the body.

It is generally believed that facial atopic dermatitis and various other facial skin diseases are associated with disturbances of skin barrier function as evidenced by an increase in TEWL, a decrease in water-binding properties, and a reduction in skin surface lipids. When chronic, inflammatory skin diseases manifest on the face, there is the challenge of reducing the lesion as quickly as possible to prevent it from worsening and further compromising the integrity of the skin involved. Because of the high sensitivity of the facial skin, what may start as a small lesion can quickly be exacerbated through physical intervention and quickly worsened. These problems can be addressed through the continual use of appropriate moisturizers, which have been shown to improve skin hydration, reduce susceptibility to irritation, and restore the integrity of the SC. Some moisturizers also supply the compromised SC with lipids that further accelerate barrier recovery. Moisturizers can serve as an important first-line therapeutic option for patients with atopic dermatitis and other chronic skin diseases [14].

Historically, moisturizers have been shown to have a steroid-sparing effect in patients with atopic dermatitis and eczema. Many of the elements in moisturizers, from lipids to emollients, have been shown to significantly improve the condition of the skin when used by patients with various dermatoses [15]. Glycerin has been implicated in the molecular mechanism controlling keratinocyte maturation, an important aspect of normal desquamation and barrier maintenance. Furthermore, its role in maintenance of hydration for the proper functioning of proteases, especially filaggrin, is critical to the successful treatment of eczemas [16,17].

Recently, a comprehensive clinical study provided evidence that moisturizers not only enhance the efficacy of topical corticosteroids in patients with atopic dermatitis, but may also prevent the recurrence of disease [15]. In general, the maintenance of the SC along with rapid repair of disruptions to the barrier that would otherwise become larger and increase inflammation and discomfort as well seem to be central tenets in the approach to treating potential dermatoses on the face with moisturization. Therefore, facial moisturizers may represent a valuable first-line treatment option for many dermatologic diseases and confer a number of important therapeutic benefits that go beyond the surface of the facial skin and have a critical role in the molecular mechanisms that maintain healthy skin.

Conclusions

Facial moisturizers fulfill an important need by providing skin comfort and alleviating dryness. Efficacious formulations contain ingredients that work directly to bring moisture to the skin, but also indirectly, as is the case with glycerin, induce the transport and retention of water molecules at the subcellular level. The goal of facial moisturizers is to enhance, or restart, the processes intrinsic to the skin's natural ability to maintain its barrier function through the multiple pathways utilizing proteases, lipids, cell differentiation and, eventually, desquamation, all while maintaining an esthetically pleasant presence.

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Chapter 17: Hand and foot moisturizers

Teresa M. Weber[1], Andrea M. Schoelermann[2], Ute Breitenbach[2], Ulrich Scherdin[2], and Alexandra Kowcz[1]

[1]Beiersdorf Inc, Wilton, CT, USA
[2]Beiersdorf AG, Hamburg, Germany

BASIC CONCEPTS

- Xerosis of the hands and feet is common, caused by a paucity of sebaceous glands.
- Moisturization of the hands and feet can prevent eczematous disease and aid in disease eradication.
- Effective moisturizers provide occlusive lipophilic substances that act as protectants and barrier replenishers, as well as hydrophilic agents that function as humectants to bind and hold water.
- Recent recognition of the role of aquaporins, special moisture regulating channels, in skin cells has provided the opportunity for a new moisturization technology, focusing on substances that stimulate and operate through aquaporins.

Introduction

The hands and feet are prone to dryness and impaired barrier function because of their unique functional roles, predisposing the skin to heightened irritant sensitivity and the development of dermatoses. Protective and regenerative moisturizing skin care is the foundation for averting and treating dry skin associated skin diseases and disorders.

Effective moisturizers provide occlusive lipophilic substances that act as protectants and barrier replenishers, as well as hydrophilic agents that function as humectants to bind and hold water. The importance of urea as a physiologic humectant and natural moisturizing factor is discussed. Application of moisturizers containing urea is shown to increase its concentration and exert ultrastuctural changes in the stratum corneum, hydrate severely compromised skin, and support and enhance barrier function. In addition, the role of aquaporins and the underlying mechanisms of moisture homeostasis of the skin are discussed vis-à-vis new opportunities to create better actives and product formulations which can help regulate moisturization from within the skin.

Moisturization needs of the hand and foot

Skin of the hands and feet is different from other body sites. In particular, skin on the palms and soles is thicker, and has a high density of eccrine sweat glands; however, it lacks apocrine glands. These sites are highly innervated and involved in most of the daily activities of life. Repetitive use of the hands and feet accompanied by pressure and friction can promote the formation of areas of thickened keratinized skin or calluses, which can crack and fissure. Site-specific requirements for hygienic care and diseases common to these sites have been described [1]. In addition, the hands and feet have special skincare needs for efficacious moisturization as well as unique requirements for formulations that are compatible with their special sensory and functional roles and needs.

Hand skin is particularly susceptible to xerosis and dermatitis. Constant use of the hands, frequent washing, and environmental, chemical, and irritant exposure can provoke these problems. Further, because the hands are especially prone to injury and exposed to irritants and pathogens, specific protectant skincare formulations can be highly beneficial to prevent irritation or occupational dermatoses such as hand eczema [2].

While the feet may be less likely to suffer from deleterious occupational exposures, environmental factors can have an impact on the moisture status of the foot skin. Cold, dry weather in winter, bare feet in summer, and the confinement of shoes can compromise the hydration state. Occlusive shoes and socks can also trap moisture and render the foot susceptible to microbial infections, especially from fungus, damaging the barrier function and dehydrating the skin. In addition, certain metabolic diseases can impact circulation and innervation of the extremities, which in turn affects skin hydration. In particular, reduced circulation and eccrine sweat gland activity in diabetics cause severe xerosis which can spiral into other severe foot problems.

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Protective and regenerative moisturizing skin care is the foundation for treating all dry skin associated skin diseases and disorders. While the underlying cause of dry skin in any specific skin disorder needs to be addressed, frequently the symptomatic control of severe xerosis by appropriate moisturizers may reduce the need for more potent treatments, such as prolonged use of topical steroids and immune modulators, which can have detrimental side effects.

Moisturizing creams containing urea have been reported to improve the physical and chemical nature of the skin surface, with the manifest benefits of smoothing, softening, and making dry skin more pliable [2]. Traditional moisturizing emulsions have utilized non-physiologic emollients, humectants, and skin protectants to rehydrate the skin and reduce moisture loss. The identification and understanding of the structure and function of the stratum corneum barrier lipids and the role of water binding physiologic substances collectively referred to as natural moisturizing factors (NMF) led to the development of formulations enriched in these actives. Recent recognition of the role of aquaporins, special moisture regulating channels, in skin cells has provided the opportunity for a new moisturization technology, focusing on substances that stimulate and operate through aquaporins.

Moisturizing formulations and technologies

For thousands of years oils, animal and vegetable fats, waxes and butters have been used to moisturize the skin. Recognized for their emollient or skin smoothing and softening properties, these substances were used to help restore dry skin to a more normal moisture balance. The first significant advancement from these simple moisturizers occurred over a hundred years ago when emulsifiers were developed to create the first stable water-in-oil emulsion [3].

A simple emulsion can be defined as a heterogeneous system that contains very small droplets of an immiscible (or slightly miscible) liquid dispersed in another type of liquid. These emulsions consist of a hydrophilic (water loving) and a lipophilic (oil loving) portion, either of which can make up the external or internal phases of the emulsion system. The external phase generally comprises the majority of the emulsion while the smaller internal phase consists of the dispersed droplets. Most commonly used moisturizer formulations are either oil-in-water (O/W) emulsion systems, where aqueous components predominate, or water-in-oil (W/O), where the majority of ingredients are non-aqueous.

Emulsifiers are necessary components of emulsion systems as water-soluble and oil-soluble ingredients are not miscible. Emulsifiers are surface active agents that reduce the interfacial tension between the two incompatible phases to create stable emulsion systems. The properties of the chosen emulsifiers determine the final emulsion type.

Major progress in recent decades has enabled the formulation of increasingly complex emulsions (e.g. water-in-oil-in-water emulsions, multilamellar emulsions), which combine and stabilize many incompatible ingredients for moisturizing products with unique delivery characteristics that are both highly effective and esthetically pleasing [4,5]. However, it is beyond the scope of this chapter to discuss the multitude of emulsion technologies which have been developed since the advent of the simple W/O system [6].

Occlusive materials and humectants are two major classes of moisturizing ingredients in many current moisturizers (Table 17.1). Occlusive materials coat the stratum corneum to inhibit transepidermal water loss (TEWL). Additionally, cholesterol, ceramides, and some essential and non-essential free fatty acids present in oils can help to replenish the natural lamellar barrier lipids that surround the squames in the stratum corneum, fortifying the barrier function of the skin. Some common examples of occlusive materials are petrolatum, olive oil, mineral oil, soybean oil, lanolin, beeswax, and jojoba oil. Petrolatum, lanolin, and mineral oil are considered occlusive materials, yet they also serve as emollients on the skin [7,8].

Humectants are materials that are capable of absorbing high amounts of water from the atmosphere and from the epidermis, drawing water into the stratum corneum for a smoother skin feel and look. Examples of well-known humectants include glycerin (or glycerol), sorbitol, urea, sodium hyaluronate, and propylene glycol. Glycerin is a widely used humectant with strong water binding capacity and holding ability, making it ideal for dry skin moisturizing formulations. Because of its importance in moisturizing products, it has been extensively reviewed elsewhere [9,10].

A number of commercially available hand and foot moisturizers incorporate combinations of both humectants and occlusive materials to deliver the optimal skin benefits (Table 17.2).

Natural moisturizing factors

The NMF are a collection of hygroscopic substances in the skin that act synergistically to confer effective water binding properties. The NMF has been reported to be composed of approximately 40% amino acids, 12% pyrrolidone carboxylic acid, 12% lactates, 7% urea, 18% minerals, and other sugars, organic acids, citrates, and peptides [11]. These substances, derived from eccrine sweat, extracellular components, largely from breakdown products of the insoluble protein filaggrin, have an important role in maintaining

Table 17.1 Key classes of commonly used moisturizing ingredients.

Key classes	Moisturizing ingredients	Function in skin
Occlusives	Petrolatum Waxes Lanolin Mineral oil Cholesterol Ceramides Triglycerides and free fatty acids Sunflower oil Soybean oil Jojoba oil Olive oil Evening primrose oil Borage oil	Moisturization by occlusion of the stratum corneum and/or replenishment of lamellar barrier lipids
Humectants	Glycerin/glycerol Sorbitol Sodium hyaluronate Propylene glycol Amino acids* Lactate* Pyrrolidone carboxylic acid* Urea* Salts*	Draws water from the formulation base, atmosphere, and from the underlying epidermis to increase skin hydration *Natural moisturizing factors – absorb large amount of water even in relatively low humidities. Provide aqueous environment for key enzymatic functions in the skin

Table 17.2 Examples of commercially available hand and foot creams.

Key ingredients		Functions and claims	
		Hand cream	**Foot cream**
I	Glycolic acid, mineral oil, petrolatum	Exfoliation and moisturization by "occlusives" to both smooth and soften skin	Exfoliation and moisturization by "occlusives" to both smooth and soften skin
II	Glycerin, shea butter, almond oil, olive oil	Moisturization of hands and softening of cuticles	Moisturizes, soothes, and protects dry, cracked, and callused heels
III	Caprylic/capric triglycerides, glycerin, sunflower oil, olive oil, almond oil	Moisturization of hands, nails, and cuticles	Soothes and heals severely dry, cracked heels
IV	Beeswax, sweet almond oil	Moisturizes and softens dry skin	Prevents and heals cracked heels, calluses, corns, blisters
V	Lanolin, allantoin, glycerin, sunscreens: avobenzone, octinoxate	Moisturizes skin and helps treat the signs of aging	
VI	Glycerin, petrolatum, dimethicone, mineral oil	Helps form a protective moisture barrier; heals and protects dry hands with 24-hour moisturization	
VII	Urea, sodium lactate, glycerin	Gently exfoliates and moisturizes; relieves dry skin associated with hand eczema	Intensively moisturizes, smoothes and heals dry, cracked feet
VIII	Prescription urea (25%, 30%, 40%, or 50%), mineral oil, petrolatum	Healing and debriding of hyperkeratotic skin and nails	Healing and debriding of hyperkeratotic skin and nails

moisture in the non-viable layers of the epidermis. Because of the moisture gradient that exists from the well-hydrated dermis to the relatively moisture-deprived stratum corneum, the cutaneous moisturization state is a function of the occlusive barrier lipids in the stratum corneum and the humectant properties of the NMF [12]. Both are critical to retain moisture and resist TEWL and the dehydrating effects of the environment. Therefore, qualitative or quantitative changes in either the barrier lipids or the NMF components can alter skin hydration.

Urea is a major constituent of the water-soluble fraction of the stratum corneum [13]. Because of the high water binding capacity of urea, the water content in the skin depends on its concentration. In dry skin and in keratinization disorders, a deficit of urea is often found in the stratum corneum, confirming its importance in skin moisture balance. The concentration of urea has been reported to be reduced by approximately 50% in clinically dry skin compared to healthy skin [14,15]. The stratum corneum of unaffected psoriatic skin reveals no deficit in urea content, but levels in psoriatic lesions are reduced by 40% [16]. However, in patients with atopic dermatitis there is a deficit of about 70% in unaffected skin and about 85% in involved skin [17]. Urea has been demonstrated to be an effective moisturizer for a range of dry skin conditions [18] and especially xerosis of the elderly [19,20]. Lodén has recently compiled a summary of clinical data on the treatment of diseased skin with urea-containing formulations [21]. Besides improvements in skin hydration, urea may be enhancing the levels of linoleic acid and ceramides [22], providing an additional skin benefit.

Urea is very soluble in water, but practically insoluble in lipids and lipid solvents. By its hydrogen-bond breaking effect, urea may expose water binding sites on keratin allowing the transport of water molecules into the stratum corneum, thereby leading to a plasticizing effect [23]. In addition, urea has proteolytic and keratolytic effects in concentrations above 10% [21]. These activities are exploited in prescription formulations of 12–50%, which are often employed for debriding purposes in keratinization disorders.

Lactic acid and salts of lactic acid, other efficacious components of the NMF, have also been used to treat dry skin conditions [11]. Like urea, the principal moisturizing effect is brought about by their humectancy. However, additional benefits of barrier support and restoration may be attributed to these NMF as an increase in ceramide synthesis in keratinocytes treated with lactic acid has been reported [24].

Ultrastructural effects

Differential changes in skin hydration state and ultrastructure after the application of various moisturizing products can be observed using scanning electron microscopy (SEM) of frozen sections from skin biopsies [25]. Figure 17.1 depicts the epidermis of skin treated with a commercial lotion with 10% urea, sodium lactate, and glycerin (right), or treated with a vehicle lotion without urea, sodium lactate, and glycerin (left). From the SEM images it could be concluded that the product penetrated the entire stratum corneum, resulting in a more compact stratum corneum layer, with a 20–40% reduction in corneocyte thickness. When compared with an untreated control (not shown), the vehicle treatment did not have an influence on the stratum corneum thickness. The compaction of the stratum corneum by the urea product suggests an improved barrier function which has been confirmed in other clinical studies demonstrating a reduction in TEWL [22].

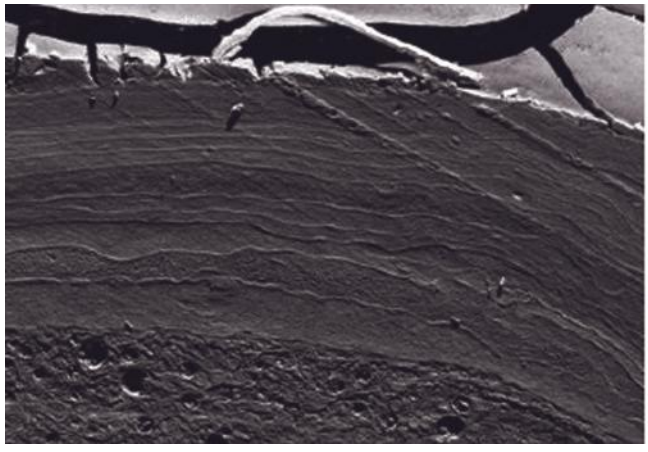
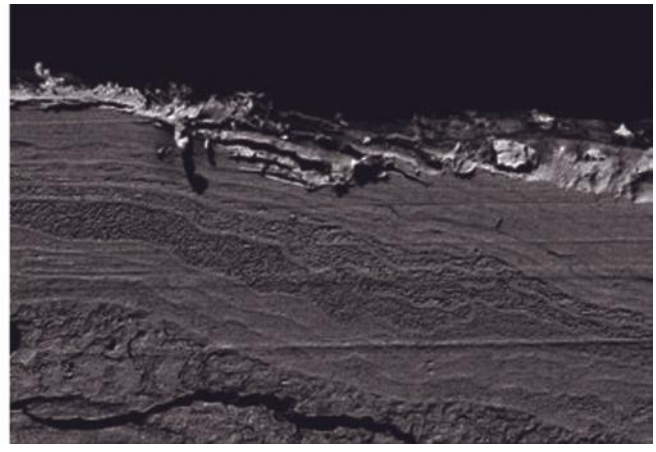
(a)   (b)

Figure 17.1 Freeze–fracture scanning electron micrographs of the stratum corneum of skin treated with a vehicle lotion (a) or the vehicle lotion containing 10% urea and sodium lactate (b).

Clinical demonstrations of product efficacy of sodium lactate and urea formulations

Hand care

Several clinical studies were conducted to evaluate the ability of a fragrance-free, O/W emulsion containing 5% urea and 2.5% sodium lactate to fortify the skin of healthy subjects, and to moisturize, protect, and treat others with compromised hand skin.

Improvements in urea content

Thirty-one volunteers with healthy skin were enrolled in this study. Subjects refrained from the use of topical treatments for a period of 1 week and then applied the test product twice daily for 2 weeks. Urea content of the skin, moisturization state, and skin roughness were assessed at baseline, after 2 weeks of treatment, and 3 days after the last application. A significant increase ($p < 0.05$) in the urea content of the skin compared with untreated skin was observed (Figure 17.2) as well as significant improvements in skin hydration levels and roughness (data not shown). Franz cell porcine skin penetration studies confirmed the penetration and distribution of urea throughout the skin compartments 24 hours after application of a 5% urea body cream formulation: 54% stratum corneum, 7% in the viable epidermis, 22% in the dermis, and 17% in the receptor phase.

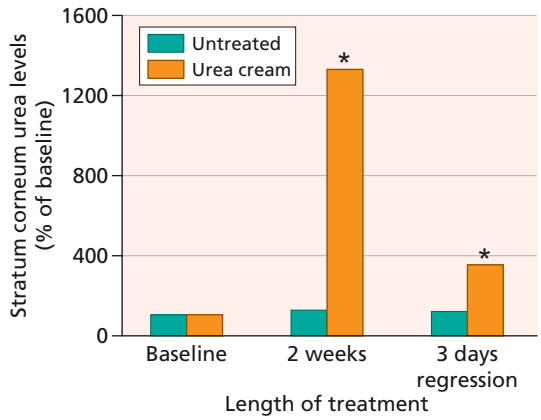


Figure 17.2 Stratum corneum urea content before application, after 2 weeks of daily use, and 3 days after discontinuing application of an oil-in-water emulsion containing 5% urea and 2.5% sodium lactate.

Table 17.3 Mean clinical grading scores at baseline and after 4 weeks of daily use of a 5% urea and sodium lactate oil-in-water emulsion.

	Cracking/fissuring	Dryness/scaling	Eczema severity
Baseline	4.78	6.61	3.04
Week 4	2.91*	3.59*	1.66*

* Significant difference relative to baseline, $p \leq 0.05$.

Improvement in eczema and xerosis

In a second 4-week controlled usage study, 23 subjects with hand eczema and 14 subjects with hand dermatitis/xerosis were enrolled. The subjects applied the test cream at least twice per day (morning and evening), and as often as needed. Clinical evaluations were made at baseline, and after 2 and 4 weeks of hand cream use for cracking/fissuring and dryness/scaling (0–8 scale), and erythema, edema, burning, stinging, and itching (0–3 scale). Subjects with eczema were also evaluated using an Investigator's Global Assessment for Eczema (0–5 scale). Digital photographs were taken at each of the clinical visits.

Significant improvements ($p < 0.05$) in clinical grading scores at week 4 relative to baseline were observed for dryness/scaling and cracking/fissuring, and the Investigators Global Assessment for Eczema (Table 17.3). Average irritation scores were also significantly reduced and negligible by week 4 for itching, stinging, and burning (data not shown).

Digital photographs captured the dry, compromised hand skin condition at the baseline visit, and demonstrated improvements that reflected the clinical assessments. Figure 17.3 shows the typical improvements observed in subjects at week 4 (right), compared with baseline (left).

In conclusion, appropriate hand care can both treat and prevent common dermatoses such as hand eczema.

Foot care

Patients with diabetes mellitus can exhibit a number of cutaneous manifestations as a result of changes in metabolic status and/or circulatory and neural degeneration [26]. Management of dry skin in these individuals is important to preserve barrier integrity which can help prevent bacterial and fungal infections. In particular, the heel skin can be very dry and scaly, prone to forming cracks and fissures which can lead to wounds that have difficulty healing.

A 6-week controlled usage study of a cream containing 10% urea, 5% sodium lactate, and glycerin as a daily treatment for the feet was conducted in 31 type I and II diabetic patients. This patient population was chosen because of their highly compromised foot skin condition. The subjects' heels were evaluated for roughness, scaling and cracking, and subjective irritation was also documented. Color photographs of the heels, taken before and after 6 weeks of treatment, documented the marked improvement in heel skin condition (Figure 17.4). In addition, significant reduction of roughness, scaling, and cracking was observed. In spite of the severely compromised skin condition at baseline, only one patient reported a mild irritation on the application site

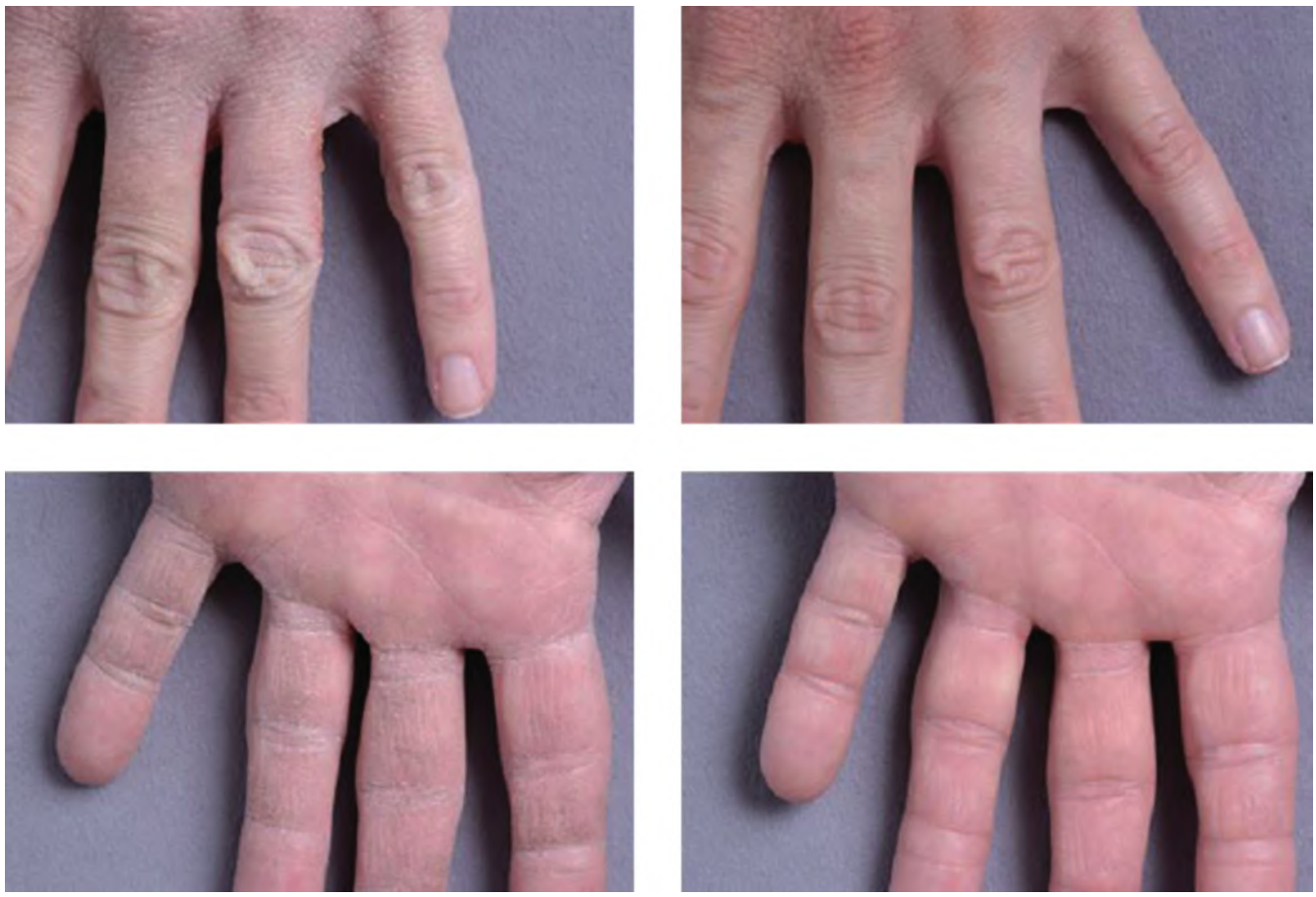


Figure 17.3 Improvement in hand eczema (top) and xerosis (bottom) after 4 weeks of daily usage (right) of a hand cream containing 5% urea and sodium lactate.

which did not interfere with his completing the study according to the protocol.

A second multicenter study of 604 patients with dry or severely dry, chapped feet and generalized xerosis (258, 42.7%), diabetes (179, 29.6%) or atopic dermatitis (113, 18.7%) was conducted in Germany and Austria. The patients applied a foot cream containing 10% urea, 5% sodium lactate, and glycerin at least twice daily for 2 weeks. While 319 patients used specific foot treatment products to care for their feet at the baseline visit, only 20 used other topical products in addition to the foot cream during the study period. The foot skin was clinically graded for xerosis, scaling, and cracking at baseline and after 2 weeks of treatment on a 5-point scale (none, slight, moderate, severe, or very severe). Table 17.4 documents the improvement in skin condition after 2 weeks of foot cream usage, showing significant and marked decreases in the percentage of patients with severe or very severe symptoms, and overall noticeable improvements in 95% of the patients. In this large patient population, the investigating dermatologists judged the tolerability to be very good or good in 96.7% of the patients, recommending continued product use.

These data and many other published studies [18–22] support the therapeutic value and excellent safety profile of urea when administered topically to treat various dry skin conditions.

The future: Next-generation moisturizers

Water homeostasis of the epidermis is important for the appearance and physical properties of skin, as well as for the water balance of the body. Skin moisture balance depends on multiple factors including external humidity, uptake of water into the epidermis, skin barrier quality, and endogenous water binding substances. Biosynthesis and degradation of skin components is also influenced by water balance, impacting the moisturization state of the epidermal layers. In recent times, aquaporins (AQP), important hydration-regulating elements in the lower epidermis, have been described [27].

The first indications of the critical importance of AQP in regulating tissue hydration came from investigations of

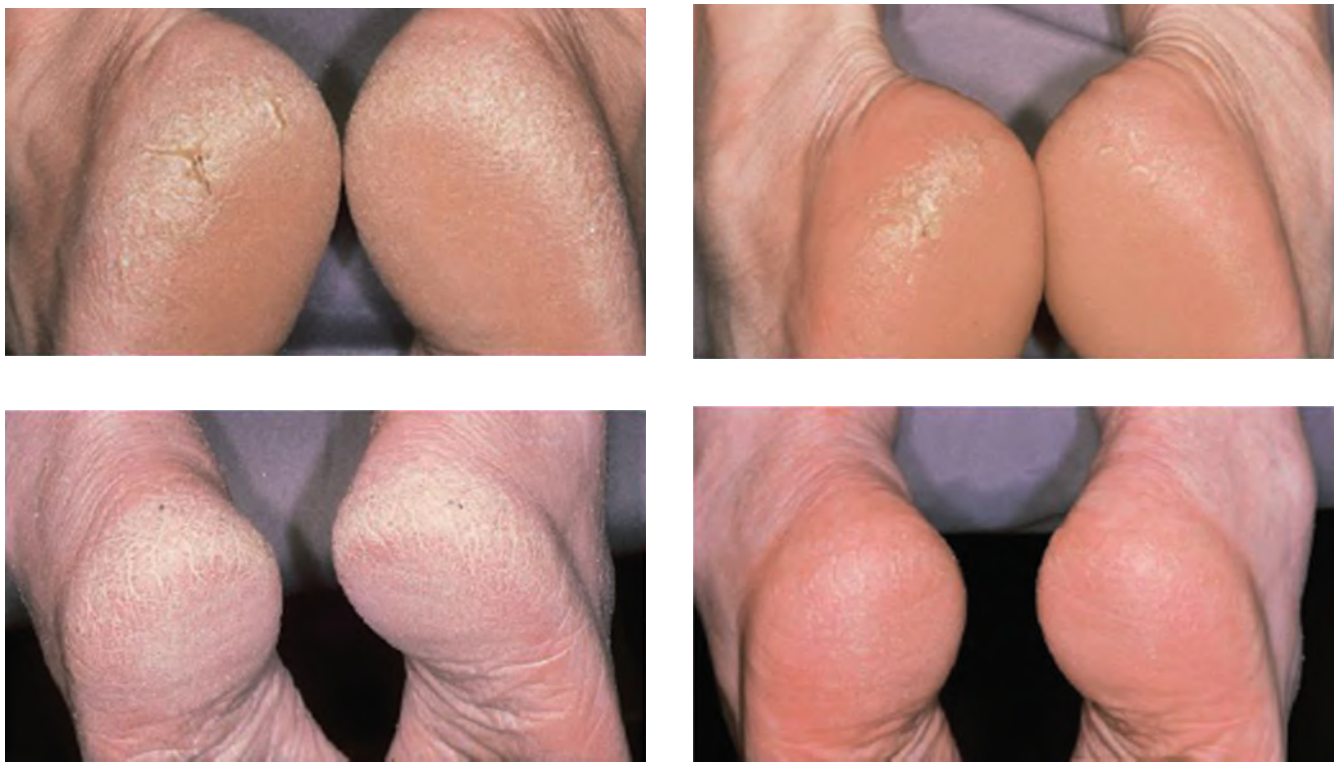


Figure 17.4 Improvement in diabetic foot skin after 6 weeks of daily usage of a foot cream containing 10% urea and 5% sodium lactate. Pretreatment photos (left) of two different subjects (top and bottom) and their corresponding week 6 photos (right).

Table 17.4 Clinical grading scores before and after 2 weeks of treatment. Percentage of patients with none or slight and severe or very severe symptoms (100% = 604 patients).

		None or slight (%)	Severe or very severe (%)
Xerosis	Baseline	5	67
	Week 2	69	6
Scaling	Baseline	22	44
	Week 2	79	6
Cracking	Baseline	26	32
	Week 2	66	8

other organ systems, in particular the kidney [28]. Since their initial discovery, AQP genes have been cloned and, to date, 13 different genes (AQP1–13) have been identified [29]. The first proof for their relevance in skin came from Ma *et al*. [30] who produced knockout mice lacking AQP3, which exhibited a reduced stratum corneum hydration. Studies confirmed the importance of these findings in dry human skin. Subjects whose epidermal barriers were damaged by a week-long tenside-based treatment that resulted in dry, compromised skin, showed a significant decrease in the number of AQP3 pores ($p = 0.04$). The pores were quantified by analysis of Western blots, and a 43% reduction in the dry skin samples was observed.

Further, in other skin conditions associated with skin dryness, a reduction in AQP3 has also been observed. Specifically, an age-related decline in AQP3 levels, as well as decreases associated with chronic sun exposure were reported [31].

Water and the moisturizing substances glycerol and urea have been found to be transported through the AQP in skin, providing moisture from within to the epidermis [32]. Expanding knowledge on the activity and regulation of AQP3 has led to the pursuit of a new class of actives that can modulate the expression of these water channels.

Enhanced glycerol derivatives

In vitro studies on human keratinocytes demonstrated a significant increase in AQP3 levels by a specific enhanced glycerol derivative (EGD), designed and synthesized to confer specific structural and osmotic properties. Figure 17.5 depicts the enhanced AQP3 levels of EGD treated human keratinocytes after 48 hours of incubation.

Additional *in vitro* studies measuring AQP3 mRNA levels in human keratinocytes confirmed these findings. In contrast to glycerol treatment, EGD increased mRNA expres-

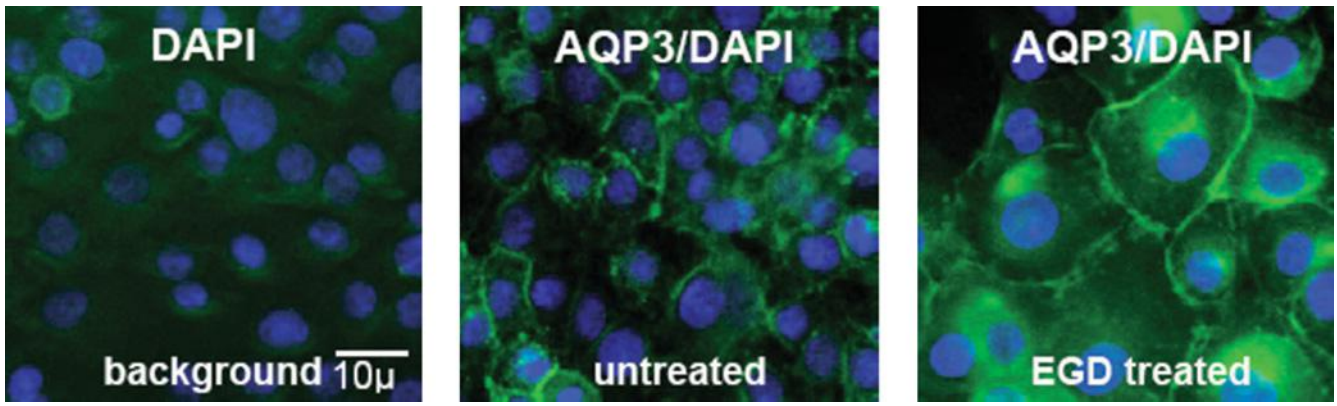
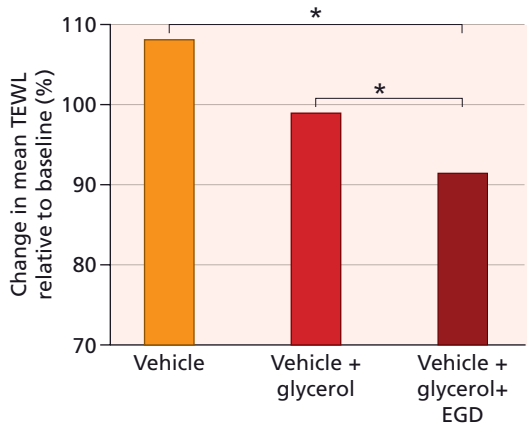


Figure 17.5 Immunohistochemical localization of the AQP3 protein in keratinocyte monolayers stained with a rabbit antihuman AQP3 antibody. Background control (left), untreated control (center), treatment with 3% enhanced glycerol derivative for 48 hours (right).



*Significantly different, $p < 0.05$.

Figure 17.6 *In vivo* study of 23 volunteers with dry skin. Transepidermal water loss (TEWL) measurement after the following treatments: vehicle; vehicle with 6.5% glycerol; and vehicle with 6.5% glycerol and 5% enhanced glycerol derivative (EGD).

sion relative to the control. Further, to assess the efficacy of this new active, *in vivo* placebo-controlled studies were conducted. Figure 17.6 demonstrates the results of a study of 23 subjects, whose epidermal barriers were damaged by a tenside-based treatment, resulting in dry, compromised skin. The restoration of the epidermal barrier was assessed weekly by measuring TEWL on treated skin sites. The applied topical test lotions included a vehicle preparation, vehicle plus 6.5% glycerol, and the vehicle with 6.5% glycerol and 5% EGD.

After damaging the skin's barrier for 1 week, vehicle treatment was ineffective at restoring the barrier to baseline levels, exhibiting greater moisture loss levels in the skin. Treatment with the glycerol-containing vehicle showed a reduction of the TEWL compared with the vehicle. However, a superior and significant barrier restoration and fortification is observed with the glycerol–EGD containing formulation compared with both vehicle and vehicle with glycerol.

Conclusions

Moisturizing substances have been used for thousands of years to improve the condition of compromised skin. The advent of stable emulsions and subsequent advancements in emulsion technologies provided improved elegance and efficacy for moisturizing products. More than 100 years of process refinements, discovery of new ingredients, and the growing understanding of the NMF and biologic mechanisms that regulate the skin's moisture balance have contributed toward products with greatly enhanced stability, esthetics, and efficacy. In contrast to ingredients that exert their effects solely from the surface of the skin, the recent discovery and understanding of the function of AQP and new appreciation of the underlying mechanisms of moisture homeostasis of the skin provides new opportunities to create even better actives and product formulations which can help regulate moisturization from within the skin.

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Chapter 18: Sunless tanning products

Angelike Galdi, Peter Foltis, and Christian Oresajo
L'Oréal Research, Clark, NJ, USA

BASIC CONCEPTS

- Tanned skin is considered attractive among fair-skinned individuals.
- Self-tanning preparations containing dihydroxyacetone (DHA) induce a temporary safe staining of the skin simulating sun-induced tanning.
- Self-tanners are formulated into sprays, lotions, creams, gels, mousses, and cosmetic wipes.
- The tanning effect of DHA begins in the deeper part of the stratum corneum before expanding over the entire stratum corneum and stratum granulosum resulting in the production of brown melanoidins.
- DHA products do not confer photoprotection unless sunscreen filters are added to the formulation.

Introduction

Social norms for tanning in the USA have dramatically changed in recent times. The presence of a tanned body at one time conveyed the social status of an outdoor laborer. Now, having a tan, especially during the winter months, indicates affluence.

More information has become available regarding the deleterious effects of UV exposure. [1–3]. The public is beginning to understand the dangers, thereby modifying their lifestyle choices towards safer practices. However, the change has been slow because sun exposure behavior is in part influenced by psychologic and societal factors [4–6]. Self-tanning preparations are becoming an increasingly important option for those desiring the tanned look but not exposing themselves to undue harm.

Sunless tanning products

Definition

Self-tanning products, or sunless tanners, are preparations that when applied topically impart a temporary coloration to the skin mimicking skin color of naturally sun-tanned skin. Depending on the formulation and the active ingredients, the onset of color formation can be anything from immediate to several hours and can last up to 1 week.

Self-tanning formulations were introduced in the 1960s. Consumers' acceptability soon waned because of unattractive results such as orange hands, streaking, and poor coloration. Because of these drawbacks, consumers today still associate sunless tanning with these undesirable results. However, improved formulations have appeared on the market. Refinements in the dihydroxyacetone (DHA) manufacturing process has aided in the creation of formulations that produce a more natural-looking color and better longevity.

Active ingredients

The most widely used and most efficacious active ingredient in self-tanners is DHA. It is the only ingredient that is currently recognized as a self-tanning agent by the US Food and Drug Administration (FDA) [7]. DHA-based sunless tanners have been recommended by the Skin Cancer Foundation, the American Academy of Dermatology Association, and the American Medical Association [8–10]. DHA is a triose and is the simplest of all ketoses (Figure 18.1).

Mechanism of action of DHA

Ketones and aldehydes react with primary amines to form Schiff bases [11]. This is similar to the Maillard reaction, also known as non-enzymatic browning, and involves, more specifically, the reaction between carbohydrates and primary amines [12].

DHA is able to penetrate into the epidermis because of its size. Pyruvic acid is formed from DHA and either can react with sterically unhindered terminal amino groups in the amino acids of epidermal proteins. The epsilon amino group of lysine and the guanido group of arginine are particularly susceptible to nucleophilic attack by the reactive carbonyl oxygen. Epidermal proteins contain high concentrations of both of these amino acids. Based on photoacoustic depth profilometry, the tanning effect of DHA begins in the deeper

Cosmetic Dermatology: Products and Procedures. Edited by Z.D. Draelos.

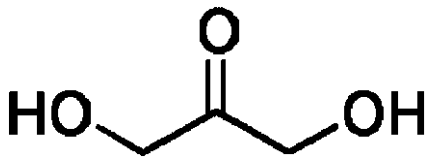

Figure 18.1 Chemical structure of dihydroxyacetone (DHA).

part of the stratum corneum layer (15–22 μm) before expanding over the entire stratum corneum and stratum granulosum [13,14]. Subsequent steps of the reaction mechanism are not fully understood. The resultant products are brown in color and are collectively referred to as melanoidins.

Alternate actives

As previously stated, US federal regulations recognize only DHA as a sunless tanning agent [7]. Alternative technologies exist, however, with the capability to impart an artificial tan to the skin.

Reducing sugars other than DHA can act as Maillard reaction intermediates and therefore have the potential for use as sunless tanning agents [15]. Reducing sugars, in basic solution, form some aldehyde or ketone. This allows the sugar to act as a reducing agent in the Maillard reaction of non-enzymatic browning. Reducing sugars include glucose, fructose, glyceraldehyde, lactose, arabinose, and maltose.

Unfortunately, a large amount of heat energy is required to trigger the glycation reaction between glucose, the most commonly known reducing sugar, and free amines. Such properties render many reducing sugars useless for sunless tanning products. An exception is the keto-tetrose, erythulose. Although this reducing sugar produces a more gradual tan than DHA, it has been utilized as a self-tanning enhancer for years.

As corporations continue to aggressively pursue new sunless tanning technologies, reducing sugars may provide the next generation of self-tanning actives.

Formulation challenges

The content of DHA in self-tanning products depends on the desired browning intensity on the skin and is normally used in the range 4–8%. Depending on the type of formulation and skin type, a tan appears on the skin about 2–3 hours after use. During product storage, the pH of a DHA-containing formulation will drift over time to about 3–4. At this pH, DHA is particularly stable. In order to ensure end product stability, certain key factors must be considered.

pH and buffers

The pH of DHA-containing formulation drops during storage. The resulting pH lies in the range of 3–4. In the past, buffering was recommended to keep the pH at a level of 4–6. However, investigations have since shown that the storage stability of DHA could be increased when formulations are kept at a pH of 3–4 and buffering at a higher pH enhances the degradation of DHA [16]. The pH of a formulation may be adjusted to approximately 3–4 by using a small amount of citric acid or using acetate buffers as they do not affect DHA stability [17].

Processing and storage of DHA

Storage and heating of DHA above 40 °C should be avoided as it causes rapid degradation. During manufacturing processes that require heating (as in the case of emulsions), DHA should not be added until the formulation has been cooled down to below 40 °C. Additionally, finished products containing DHA should be sold in opaque, or other UV-protective packaging, as well as resealable packaging, to limit exposure to air.

Nitrogen-containing compounds

Amines and other nitrogen-containing compounds should be avoided in DHA-containing formulations. This includes collagen, urea derivatives, amino acids, and proteins. The reactivity of DHA towards these compounds can lead to its degradation, therefore resulting in the loss in efficacy and acceptability of resulting color. However, some commercial formulations combine DHA with nitrogen-containing containing compounds (e.g. amino acids). This combination provides a perceptual advantage to customers as provides within tanning 1 hour as a result of the accelerated reaction between DHA and amino acids. This tan is not substantive, however, and most of it is easily washed off [17].

Sunscreens

A tan achieved with DHA alone does not offer sun protection comparable to that of sunscreens. However, it is possible to combine DHA with sunscreens to achieve a product with sun protection. Inorganic sunscreens such as titanium dioxide, zinc oxide, and nitrogen-containing sunscreens should be avoided as they induce rapid degradation of DHA.

As a final stability check, periodic determination of DHA dosage is recommended to ensure end product and long-term stability and efficacy. A simple high performance liquid chromatography (HPLC) method exists using an amine column with acetonitrile/water (75 : 25) as a mobile phase. Detection is at 270 nm.

Delivery vehicles

Creams and lotions

Self-tanning creams and lotions tend to be the most widely used of all of the self-tanning vehicles. Our studies have confirmed that although conventional, creams and lotions are preferred by consumers because of their ease of use and

reduced likelihood of having streaky color results. This is most likely because of the extended play time (e.g. rub-in time) offered by cream and lotion vehicles.

In selecting the appropriate ingredients for formulation, the use of non-ionic emulsifiers is recommended over ionic emulsifiers because of improved stability of the DHA [16]. Additionally, xanthan gum and polyquaternium-10 may be used for thickening emulsions.

Emollients have an important role in many self-tanning formulations as they impart hydration to the skin, play time during application, and a smooth and silky after feel. Types of emollients include oils, waxes, fatty alcohols, silicone materials, and certain esters.

Emulsions with DHA are particularly susceptible to microbial attack. Parabens, phenoxyethanol, and mixtures thereof are recommended [16].

Gels and gelees

Thickening formulations containing DHA, particularly to produce a clear gel, is relatively difficult because many of the conventional thickeners are not compatible with DHA. Studies have found that hydroxyethylcellulose, methylcellulose, and silica are good choices, whereas carbomers, PVM/MA decadiene crosspolymer, and magnesium aluminum silicate are not acceptable as they cause rapid degradation of DHA [16].

Silicones such as dimethicone and cyclomethicones have increased in popularity over recent years, particularly for producing water-in-silicone emulsions (typically classified as gelees). Gelees are similar in appearance to gels; however, they tend to offer improved play time and skin feel over gels as they contain high levels of the silicone emollients.

Regulatory considerations

The US FDA considers sunless tanning actives as color additives as they impart color to the skin. According to 21CFR70, color additives are defined as: "A dye, pigment, or other substance…that, when added or applied to a food, drug or cosmetic or to the human body or any part thereof, is capable (alone or through reaction with another substance) of imparting a color thereto" [18].

The actives permitted in the sunless tanning products in the USA are limited to those approved for use as such. The following color additives appear in the Code of Federal Regulations in Tables 18.1 and 18.2.

Labeling requirements are also specified under current FDA guidelines. All sunless tanning products that do not contain sun protection factor (SPF) protection must be labeled with the following warning statement (US Code of Federal Regulations): "Warning – This product does not contain a sunscreen and does not protect against sunburn. Repeated exposure of unprotected skin while tanning may increase the risk of skin aging, skin cancer and other harmful effects to the skin even if you do not burn" [18].

Table 18.1 Color additives exempt from certification per 21CFR73 2003 (US Code of Federal Regulations).

Aluminum powder	Copper powder	Luminescent zinc
Annatto	Dihydroxyacetone	Manganese violet
β-Carotene	Disodium EDTA copper	Mica
Bismuth citrate	Ferric ammonium ferrocyanide	Potassium sodium copper
Bismuth oxychloride	Ferric ferrocyanide	Pyrophyllite
Bronze powder	Guaiazulene	Silver
Caramel	Guanine	Sulfide
Carmine	Henna	Titanium dioxide
Chromium oxide greens	Iron oxides	Ultramarines
Chlorophyllin	Lead acetate	Zinc oxide

Table 18.2 Color additives per 21CFR73 2003 (US Code of Federal Regulations).

Citrus Red No. 2	D&C Red No. 17	D&C Yellow No. 10
D&C Blue No. 4	D&C Red No. 21	D&C Yellow No. 11
D&C Blue No. 6	D&C Red No. 22	Ext. D&C Violet No. 2
D&C Blue No. 9	D&C Red No. 27	Ext. D&C Yellow No. 7
D&C Brown No. 1	D&C Red No. 28	FD&C Blue No. 1
D&C Green No. 5	D&C Red No. 30	FD&C Blue No. 2
D&C Green No. 6	D&C Red No. 31	FD&C Red No. 3
D&C Green No. 8	D&C Red No. 33	FD&C Red No. 4
D&C Orange No. 4	D&C Red No. 34	FD&C Red No. 40
D&C Orange No. 5	D&C Red No. 36	FD&C Yellow No. 5
D&C Orange No. 10	D&C Red No. 39	FD&C Yellow No. 6
D&C Orange No. 11	D&C Violet No. 2	Orange B
D&C Red No. 6	D&C Yellow No. 7	Phthalocyaninato2-Copper
D&C Red No. 7	D&C Yellow No. 8	

Product attributes

Coloration

The onset of coloration starts at approximately 2–3 hours and will continue to darken for 24–72 hours after a single application, depending on formulation and skin type.

Because DHA forms covalent bonds with epidermal proteins, the tan will not sweat off or wash away with soap or water. The color gradually fades over 3–10 days, in conjunction with stratum corneum exfoliation. Any product or process that increases the rate of cell turnover or removes portions of the stratum corneum will decrease the longevity of the color. Thus, preparations containing alpha- and beta-hydroxyacids and retinoids, as well as microdermabrasion creams and the process of shaving, decrease the longevity of coloration from self-tanning products.

Evaluation

Various spectrophotometric methods can be used to evaluate the coloration parameters of self-tanners such as onset of color and longevity of color. The most popular is the L*a*b* standard from Commission Internationale d'Eclairage (CIE). The three coordinates of CIELAB represent the lightness of the color (L* = 0 yields black and L* = 100 indicates diffuse white), its position between red/magenta and green (a*, negative values indicate green while positive values indicate magenta), and its position between yellow and blue (b*, negative values indicate blue and positive values indicate yellow). The total color difference between any two colors in $L^*a^*b^*$ can be approximated by treating each color as a point in a three-dimensional space (with three components: L^*, a^*, b^*) and taking the Euclidean distance between them (ΔE). ΔE is calculated as the square root of the sum of the squares of ΔL^*, Δa^* and Δb^* [19]. It is generally recognized that $1.5\,\Delta E$ units is the minimal difference detectable to the eye. Comparisons to baseline readings can yield onset of tanning (usually readings at 30 minutes, 60 minutes, etc.) and longevity of tanning (readings at 48 hours, 72 hours, etc.).

Moisturization

The recent trend in cosmetic products is to be multifunctional. Moisturizing formulations are increasing in popularity in keeping with this trend. Formulations with 8–24 hour hydration claims are not uncommon. Current self-tanners are formulated into sprays, lotions, creams, gels, mousses, and cosmetic wipes. In general, there are no obstacles to obtaining satisfactory levels of hydration, although there are some compromises that may have to be made. Alcohol is often incorporated to achieve quick-drying formulations. The trade off is sacrificing some level of hydration. This can be offset with humectants such as glycerin or sodium hyaluronate.

Trends in sunless tanning

Daily use moisturizers/glow

Face and body moisturizers with low levels of DHA have grown in popularity over the past 5 years. Although not new to the market, the concept of using a daily moisturizer that imparts gradual color was particularly well-received by the faint in heart who were afraid of making mistakes and/or turning orange with the use of traditional sunless tanners. Typically formulated with 1–3% DHA, glow moisturizers are easy to apply and, depending on the formulation and user's skin tone, may impart a darker shade to the skin after 1–3 applications.

No-rub mists

No-rub sunless tanning mists have been sought out as the less expensive alternatives to the airbrushing trend. These multiangle applicator systems allow for simple, even, and often hands-free application. The formulation base systems are typically hydroalcoholic or aqueous solutions, therefore allowing for quick-drying properties.

Sunless tanning products with UV protection

The tan imparted by sunless tanners is not adequate to protect against UVB and UVA damage. Sunless tanners must therefore carry the required FDA warning statement [19]. Sunless tanning products that do contain sunscreen are growing in popularity because of their multifunctional properties.

Conclusions

With an increasing awareness of the harmful acute and chronic effects of UV damage, sunless tanning use remains a popular alternative to tan seekers. Modern day formulations are efficacious, well-tolerated, easy-to-use, and provide natural looking results. A probable increase in patient compliance of safe sun practices can therefore be anticipated.

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Chapter 19: Sunscreens

Dominique Moyal,[1] Angelike Galdi[2], and Christian Oresajo[2]

[1] L'Oréal Recherche, Asnières, France
[2] L'Oréal Research, Clark, NJ, USA

BASIC CONCEPTS

- Sunscreens provide photoprotection from UV radiation (UVR).
- Photoprotection is required for both UVB and UVA radiation.
- Organic and inorganic filters are used in sunscreens.
- Sunscreen filters must be carefully combined to achieve esthetically pleasing products with photostability and broad spectrum photoprotection.

Introduction

Human exposure to UVR from sunlight can cause many adverse effects. They involve both UVB (290–320 nm) and UVA (320–400 nm). UVB radiation is mainly responsible for the most severe damage: acute damage such as sunburn, and long-term damage including cancer. It has a direct impact on cell DNA and proteins [1]. Unlike UVB, UVA radiation is not directly absorbed by biologic targets [2] but can still dramatically impair cell and tissue functions:

- UVA penetrates deeper into the skin than UVB. It particularly affects connective tissue where it produces detrimental reactive oxygen species (ROS). ROS cause damage to DNA, cells, vessels, and tissues [3–8].
- UVA is a potent inducer of immunosuppression [9,10] and there is serious concern about its contribution in the development of malignant melanoma and squamous tumors [11,12].
- Photosensitivity reactions and photodermatoses are primarily mediated by UVA [13].

As a result, a major concern has been raised that most available sunscreen products are incapable of preventing the harmful effects of UVA. It is important to note that under any meteorologic condition, the UVA irradiance is at least 17 times higher than the UVB irradiance.

For all these reasons, it is evident that sunscreens must contain both UVA and UVB filters to cover the entire range of harmful radiation.

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Regulatory status of sunscreens

With increased knowledge about UV-induced skin damage and particularly the effects of UVA, public education programs have been developed with an emphasis on the proper use of sunscreen products. Many new UV filters have been made available in the last decade with improved efficacy and safety. The availability of new filters has been slow in some countries for regulatory reasons. An example is the USA where certain UVA and UVB filters, which are marketed elsewhere, are not approved for use. The availability of efficient sunscreen products depends not only on the regulatory status of the UV filters but also on the ability to inform the consumer about product efficacy with appropriate labels based on sun protection factor (SPF) and UVA protection levels.

Sunscreen products can be classified in two main categories according to their purpose:

1 *Primary sunscreens.* Products whose main purpose is the protection of the skin from the effects of the sun, such as beach sunscreens and products used for outdoor activities.

2 *Secondary sunscreens.* Products that have a primary use other than skin protection, such as daily moisturizing creams, antiwrinkle/antiaging creams, and whitening skin products. In these products, sun protection is necessary to optimize the claimed effect. For this category of products, sun protection is an additional claim but not the main purpose.

Sunscreen classification

Sunscreen products can also be classified in terms of regulatory status. Sunscreen products are ordinary cosmetic products in Europe, EU and non-EU countries (e.g. Russia), most African and Middle-Eastern countries, India, Latin America,

and Japan. They can be classified "special" cosmetic products as in China (special cosmetics), Korea and Ethiopia (functional cosmetics), South Africa (under SABS standard), Australia (under standards) [14], and Taïwan (medicated cosmetics). They are over-the-counter (OTC) drugs in the USA [15] (all sunscreens and products with SPF). In Canada, they can be either OTC drugs or natural health products (NHP), in this case the sunscreen contains only "natural" active ingredients: titanium dioxide, zinc oxide.

Approved UV filters

In Europe, the UV filters are listed in Annex VII of the Cosmetics Directive. There are 27 UV filters on this list. In the USA, there are 16 filters included in the sunscreen monograph (Table 19.1). There are two main regulatory methods to market OTC products: monograph or a New Drug Application (NDA). An NDA is necessary to obtain the approval of a formula containing a new UV filter, or a new concentration for an approved active, or a new mixture of approved actives.

A Time and Extent Application (TEA) is a new procedure for an active ingredient already approved abroad. It allows the FDA to accept commercial data obtained on external markets in place of use of an authorized drug on the US market; however, toxicologic data requirements for a TEA are very similar to those for an NDA.

Seven UV filters are currently eligible for evaluation through a TEA procedure (not yet finalized):

1 Isoamyl *p*-methoxycinnamate (amiloxate) 10% max.
2 Methyl benzylidene camphor (enzacamene) 4% max.
3 Octyl triazone 5% max.
4 Methylene bis-benzotriazolyl tetramethylbutylphenol (Tinosorb® M, Ciba, Basel, Switzerland).
5 Bis-ethylhexyloxyphenol methoxyphenol triazine (Tinosorb® S, Ciba, Basel, Switzerland).
6 Diethylhexyl butamido triazone 3% max 7 Terephthalylidene dicamphor sulfonic acid (Ecamsule, Mexoryl® SX).

In Australia, 26 UV filters are accepted by Therapeutic Goods Administration (TGA) and in Japan 31 UV filters are allowed.

When comparison is made between the common UV filters approved in Europe and USA, only 11 filters are common, but *p*-aminobenzoic acid (PABA) will most likely be deleted in Europe and terephtalilydene dicamphor sulfonic acid (TDSA) is only available in USA under NDA for four formulas.

Because of the importance of being well protected against UVA radiation, there are many new UVA filters or broad UVB/UVA filters, which have been developed and authorized in Europe, Australia, and Japan. It is obvious that the number of these filters is limited in the USA (Table 19.2). In addition, there are some limitations in the use of avobenzone in the USA. Combinations with some other UV filters, such as titanium dioxide and enzulizole, are not permitted and the maximum use level according to the sunscreen monograph is limited to 3%.

Table 19.1 Sunscreen approved in the USA.

Sunscreen approved in USA	Maximum concentration (%)
p-Aminobenzoic acid (PABA)	15
Avobenzone	3
Cinoxate	3
Dioxybenzone	3
Ensulizole (phenylbenzimidazole sulfonic acid)	4
Homosalate	15
Meradimate (menthyl anthranilate)	5
Octinoxate (octyl methoxycinnamate)	7.5
Octisalate (octyl salicylate)	5
Octocrylene	10
Octyl dimethyl PABA	8
Oxybenzone	6
Salisobenzone	10
Titanium dioxide	25
Trolamine salicylate	12
Zinc oxide	25

Development of sunscreens

A proper sunscreen product must fulfill the following critical requirements:

- Provide efficient protection against UVB and UVA radiation;
- Be stable to heat and to UVR (photostable);

Table 19.2 Regulatory approval status for the main UVB/UVA and UVA filters.

Benzophenone Oxybenzone	EU, Japan, Aus, Can, USA
BMDM (avobenzone)	EU, Japan, Aus, Can, USA
TDSA (Mexoryl SX)	EU, Japan, Aus, Can, USA (NDA)
DTS (Mexoryl XL)	EU, Japan, Aus, Can
DPDT (Neo-Heliopan AP)	EU, AUS
DHHB (Uvinul A+)	EU, Japan
MBBT (Tinosorb M)	EU, Japan, Aus
BEMT (Tinosorb S)	EU, Japan, Aus
Titanium dioxide	EU, Japan, Aus, Can, USA
Zinc oxide	Japan, Aus, Can, USA

• Be user-friendly to encourage frequent application and provide reliable protection; and
• Be cost-effective.

In order to protect against both UVB and UVA, the sunscreen product must contain a combination of active ingredients within a complex vehicle matrix.

Active ingredients can be either organic or inorganic UV filters. According to their chemical nature and their physical properties, they can act by absorption, reflection, or diffusion of UVR.

Organic UV filters

How do organic filters work?

Organic filters are active ingredients that absorb UVR energy to a various extent within a specific range of wavelength depending on their chemical structure [16]. The molecular structure responsible for absorbing UV energy is called a chromophore. The chromophore consists of electrons engaged into multiple bond sequences between atoms, generally conjugated double bonds. An absorbed UV photon contains enough energy to cause electron transfer to a higher energy orbit in the molecule [16]. The filter that was in a low-energy state (ground state) transforms to a higher excited energy state. From an excited state, different processes can occur:

• The filter molecule can simply deactivate from its excited state and resume its ground state while releasing the absorbed energy as unnoticeable heat.
• Structural transformation or degradation may occur and the filter losses its absorption capacity. The filter is then said to be photo-unstable.
• The excited molecule can interact with its surroundings, other ingredients of the formula, ambient oxygen, and thus lead to the production of undesirable reactive species. The filter is said to be photoreactive.

The control of filter behavior under UV exposure is a critical point that needs to be investigated when new sunscreen products are developed.

Inorganic UV filters

Pigment grade powders of metal oxides such as titanium dioxide or zinc oxide have been used for many years in combination with organic filters to enhance protection level in the longer UVA range. Unlike organic filters, they work by reflecting and diffusing UVR. However, as a result of the large particle sizes, these powders also diffuse light from the visible range of the sun spectrum and they tend to leave a white appearance on the skin. To overcome this drawback, which affects cosmetic acceptance, micronized powders of both titanium dioxide and zinc oxide have been made available. However, micronization leads to changes in the protective properties of titanium dioxide: the smaller particles shift the protection range from the longer UVA toward the UVB.

Zinc oxide has better absorption in the long UVA than titanium dioxide, but it is not very efficient. Because of possible photocatalytic activity, inorganic particles are frequently coated with dimethicone or silica for maintenance of their efficacy. When nanosized titanium dioxide (<100 nm) is combined with organic UV filters, it allows high SPF products to be formulated with a lower dependence on organic UV filters. In combination with organic UV filters, nanosized titanium dioxide has more a synergistic rather than only an additive effect.

Steps toward more efficient sunscreens

As far as UVB protection is concerned, a large choice of filters has been available for a number of years. They are photostable except for the most common, ethylhexyl methoxy cinnamate (EHMC). The choice of UVA filters depends on the countries and is limited in the USA, as already explained. Inorganic pigments offer poor protection against UVA when used alone. Benzophenones are photostable but they are primarily UVB filters with some absorption in the short UVA range (peak at 328 nm).

Butyl methoxy dibenzoyl methane (BMDM or avobenzone) has a high potency in the UVA1 range peaking at 358 nm; however, it undergoes significant degradation under UV exposure and this leads to a decrease in its protective UVA efficacy. Research on the photochemistry of filters has led to the identification of some potent photostabilizers (e.g. octocrylene) of avobenzone and the development of new UVA filters that have a photostable structure. Recently, in 2005, diethylamino hydroxybezoyl hexyl benzoate (DHHB) was approved in Europe and Japan. This UVA1 filter has UV-spectral properties similar to BMDM but DHHB is photostable.

In order to provide full protection in the entire UVA range, it is necessary to have efficient absorption in the short UVA range. TDSA or Mexoryl SX™ (Chimex, Le Thillay, France), with a peak at 345 nm at the boundary between short and long UVA wavelengths, was first approved in Europe in 1993. This was followed by the approval of the broad UVB/UVA filter drometrizole trisiloxane (DTS or Mexoryl XL) with two peaks (303 and 344 nm) in 1998. Since 2000, other short UVA (disodium phenyl dibenzimidazole tetrasulfonate [DPDT] or Neo-Heliopan AP®, Symrise, Holzminden, Germany, peak at 334 nm) and broadband UVB/UVA filters (MBBT, Tinosorb M and BEMT, Tinosorb S) have been approved in Europe. All these filters are photostable.

UV filters are either hydrophilic or lipophilic. When combined a synergetic effect can be observed. This property is used to obtain higher efficacy against UVB and UVA radiation.

Combinations of highly efficient and photostable filters provide an optimally balanced protection against both UVA and UVB [17]. Studies [18–20] have shown that the protection against UV induced skin damage provided by sunscreen

products with same SPF but different UVA protection factor is markedly different, emphasizing the importance of high UVA protection in preventing cell damage. Only well-balanced, photostable sunscreens with absorption over the entire UV spectrum of sun radiation have been able to maintain intact essential biologic functions.

Formulation types

Emulsions are the most popular of sunscreen vehicles. They offer versatility of texture (cream, lotion, milk) while exhibiting good performance. Emulsions can be placed into two main categories, oil-in-water (O/W) and water-in-oil (W/O). The W/O emulsions are intrinsically very water-resistant and will consistently yield higher SPF for the same concentration of sunscreen actives when compared with O/W emulsions. However, O/W emulsions are, by far, more widely used in sunscreens. This may be explained by the lower inherent cost for an O/W vehicle (where water is the outer phase) versus a W/O (where oil, a more expensive ingredient, is the outer phase).

Aerosol spray vehicles have grown in popularity over the past few years. The multiposition spray nozzles allow for quick and easy application. Attention needs to be taken, however, that enough product is applied to ensure adequate protection. Oil, gel, stick, and mousse vehicles have decreased in popularity among formulators and consumers for several reasons. They are typically oil or wax-based, which makes then rather expensive and less efficacious. Additionally, they tend to be oily and greasy which result in lower usage and compliance.

Evaluation of the efficacy of sunscreen products

Evaluation methods must take into account the photo-instability of products in order to avoid an overestimation of protection. *In vivo* SPF and *in vivo* UVAPF (Persistent Pigment Darkening) test methods take photodegradation into account. Appropriate UV doses are used to induce erythema on human skin for SPF determination or pigmentation for UVAPF determination.

When *in vitro* methods are used they should also take into account this phenomenon to provide relevant evaluation [21].

Evaluation of the sun protection factor

The international test method for SPF determination was first introduced in 2003. This method was published jointly by the Japanese Cosmetic Industry Association (JCIA), the European Cosmetic Industry Association (Colipa), and the Cosmetic Industry Association from South Africa (CTFA SA). In 2006, a revised version of this method was published with the support of the Cosmetic Toiletries and Fragrance Association (CTFA) from the USA [22]. In 1999, the US Food and Drug Agency (FDA) published a final monograph [15]. FDA received comments and in August 2007 published a proposal of amendments [23]. This proposal includes a new SPF cap at 50+ and some amendments on technical points made in the 1999 monograph on sunscreen products.

The Australian standards on SPF testing published in 1998 are similar to the other methods [14]. The International Standard Organization (ISO) TC217 WG7 working group is currently dealing with the standardization of a SPF method. The future ISO standard will be based on the international SPF test method including some improvements and it is expected to be published at the end of 2009.

Determination of UVA protection level

The EU issued a recommendation on September 22, 2006 [24] to use a persistent pigment darkening (PPD) method similar to the JCIA method [25] or any *in vitro* method able to provide equivalent results. In addition, the critical wavelength [26] must be at least 370 nm. The EU Commission also recommends that the method used should take into account photodegradation.

The first country that published an official *in vivo* method to assess UVA protection level was Japan. The JCIA adopted the PPD method as the official method for assessment of the UVA efficacy of sunscreen products in January 1996 [25]. Korea and China also adopted this method in 2001 and 2007, respectively. The PPD method was officially recommended by European Commission in September 2006 [24] and was recently proposed by FDA in the 2007 Sunscreen Monograph Amendment [23]. The method has been described with some minor differences by different countries or authorities. Finally, UVA method is currently in progress for standardization through the ISO.

Since the PPD response requires doses greater than 10 J/cm^{-2} (approximately 40 minutes of midday summer sunlight), the photostability of sunscreens is also challenged during the test procedure. To illustrate this point, avobenzone (BMDM, Parsol®1789) was tested [27] at concentrations of 1.0, 3.0, and 5.0% individually and in combination with 10% of octocrylene, a UVB filter, known to stabilize BMDM. The results of UVA-PF of avobenzone alone ranged from 2.2 with 1% BMDM to 4.6 with 5% BMDM. In combination with 10% octocrylene the results ranged from 4.6 with 1% BMDM to 10.6 with 5% BMDM. It is evident that UVA protection efficacy of avobenzone is significantly increased when it is combined with octocrylene, compared with the same concentration of BMDM alone. This can be explained by the fact that the PPD UVA doses affect the photostability of BMDM. It has been verified under real sun exposure conditions that when a photo-unstable product applied at 1 mg/cm^2 is exposed to a UVA dose of about 30 J/cm^2 (about 2.5 hours) there is a dramatic decrease of the UVA absorption properties of avobenzone leading to a decrease of the UVA protection efficacy [28].

Critical wavelength method

An *in vitro* approach to measure UVA protection using a thin film technique was proposed by Diffey *et al.* [26]. The UVB and UVA absorbance of the product is measured on a film of product applied on a substrate which can be quartz or polymethyl methacrylate (PMMA). The method yields a measure of the "breadth" of UVA protection using a test method called "critical wavelength" [26]. In this test proposal, the absorbance of the thin film of the sunscreen is summed (starting at 290 nm) sequentially across the UV wavelengths until the sum reaches 90% of the total absorbance of the sunscreen in the UV region (290–400 nm). The wavelength at which the summed absorbance reaches 90% of total absorbance is defined as the "critical wavelength" and is considered to be a measure of the breadth of sunscreen protection.

The critical wavelength λ_c is defined according to equation (19.1):

$$\int_{290}^{\lambda_c} \lg[1/T(\lambda)]\,d\lambda = 0.9 \cdot \int_{290}^{400} \lg[1/T(\lambda)]\,d\lambda \qquad \text{(equation 19.1)}$$

Because this is a relative measurement, the "absolute" absorbance of the sunscreen is not necessary, eliminating the operator dependence of the test method. Critics of the methods based on absorbance criteria point to the fact that it is not a true measurement of UVA protective potency of the test product. The critical wavelength determination (λ_c) addresses the broadness of the protection rather than the specific protection in the UVA. Products with widely different *in vivo* protection indices (i.e. UVAPF PPD) can have identical critical wavelengths [29]. Combining both the *in vivo* PPD method for measuring the level of UVA protection efficacy and the critical wavelength method to measure the broadness of UVA absorbance has been proposed for UVA protection assessment of sunscreen products by the European Commission [24]. Other studies have shown that the higher the UVA protection level as assessed by the PPD method the better the protection against damage induced by UVA radiation [18–20]. On the other hand, critical wavelength higher than 370 nm is not a sufficient, reliable criterion to ensure that a product can provide efficient protection against UVA damage.

Conclusions

It is important that a minimal proportionality between UVA and UVB protection be ensured in order to avoid high UVB protection with low UVA protection. A UVAPF : SPF ratio of at least one-third as defined by the European Commission [24] should be universally adopted for harmonization of consumer protection. In order to reach balanced protection, combination of UV filters is necessary. The criteria of choice are the following: UV filters with different maximum absorbance peaks (UVB, short UVA, and long UVA) to cover the entire UV spectrum, appropriate filters in different phases of sunscreen emulsion (lipophilic and hydrophilic), and ensuring the photostability of the UV filters. A high level of efficacy and protection against UVB and UVA radiation can be achieved by using available new filters.

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Part 3: Personal Care Products

Chapter 20: Antiperspirants and deodorants

Eric S. Abrutyn
TPC2 Advisors Ltd. Inc. Boquete, Chiriqui, Republic of Panama

BASIC CONCEPTS

- Antiperspirants are US Food and Drug Administration (FDA) regulated drugs to be used in the underarm axilla vault only.
- Antiperspirants are primarily complexes of aluminum (e.g. Aluminum Chlorohydrate) and aluminum zirconium (e.g. Aluminum Tetrachlorohydrex-GLY).
- Deodorants, not to be confused with antiperspirants, are cosmetics and do not typically contain any aluminum-type salt complexes.
- Antiperspirants are associated with few dermatologic issues; slightly irritating under certain conditions, but *not* scientifically associated with breast cancer or Alzheimer disease.

Introduction

This chapter deals with the technologies for wetness and odor protection of the human axilla, how they are applied, and potential adverse effects of use of these products on a regular basis. Antiperspirants and deodorants have been used for centuries,[1] evolving from simple fragrances that masked offensive odors to today's complex ingredients based on aluminum and zirconium chemistries that act to slow or diminish sweat production. Odors (scents) and sweating have a biologic significance. Body scents are primeval and most likely evolved genetically to attract the opposite sex. Sweating is regulated by the sympathetic nervous system and is an important body temperature regulator, especially in warm weather climates or during heavy exercise, and functions to remove waste and toxic by-products of the body. The axilla area of the body represents a small contribution to sweating to control body temperature and removal of biologic by-products, so the controlling of sweat from this area has less health risks than other portions of the body. There is little scientific evidence that supports the use of antiperspirants, based on aluminum or aluminum–zirconium chemistry causes appreciable lasting adverse effects other than possible temporary and reversible irritation.

[1]Over 5500 years ago, every major civilization has left a record of its efforts to mask body odors. The early Egyptians recommend following a scented bath with an underarm application of perfumed oils (special citrus and cinnamon preparations).

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Physiology

Sweat glands and how they work

Sweat by itself is odorless and only establishes a characteristic odor when exposed to moisture (humidity) in the presence of bacterial flora on the skin surface, breaking down the sweat's composition and resulting in unpleasant odors. The use of antimicrobial agents is a good defense in preventing odor development from bacteria and yeast present on the skin. Another defense is the reduction of excretion from the eccrine gland to minimize the appearance of uncomfortable or unsightly wetness production.

According to *Gray's Anatomy* [1], most people have several million sweat glands distributed over their bodies, to include the underarm axilla and thus providing plenty of opportunity for underarm odors to develop. Skin has two types of sweat glands: eccrine glands and apocrine glands (Figures 20.1 and 20.2). Eccrine glands open directly on to the surface of the skin and exude sweat in the underarm, subsequently contributing to odor formation. These glands are located in the middle layer of the skin called the dermis, which is also made up of nerve endings, hair follicles, and blood vessels. Sweat is produced in a long coil embedded within the dermis where the long part is a duct that connects the gland to the opening (pore) on the skin's surface. When body temperature rises, the autonomic nervous system stimulates these

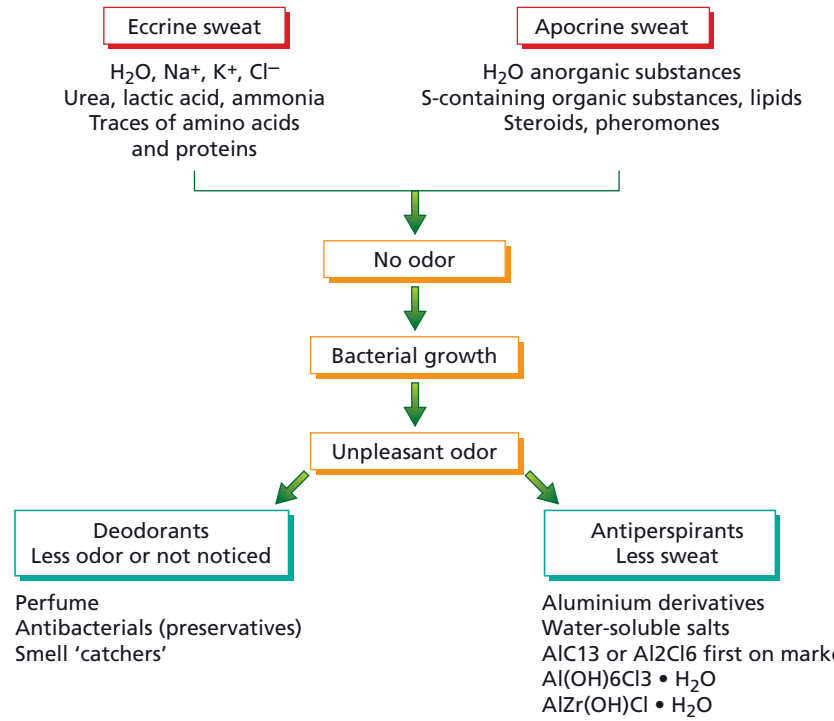

Figure 20.1 Underarm sweat gland mechanism.

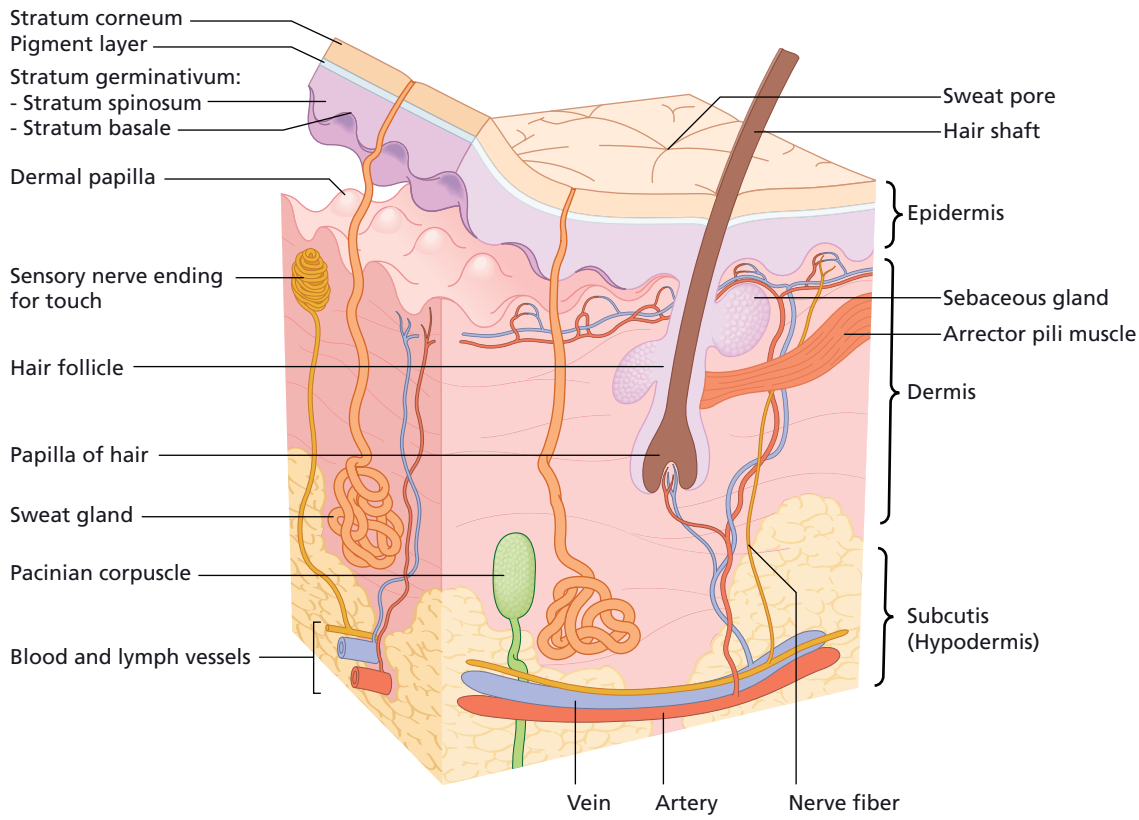

Figure 20.2 Cross-section of skin and sweat glands.

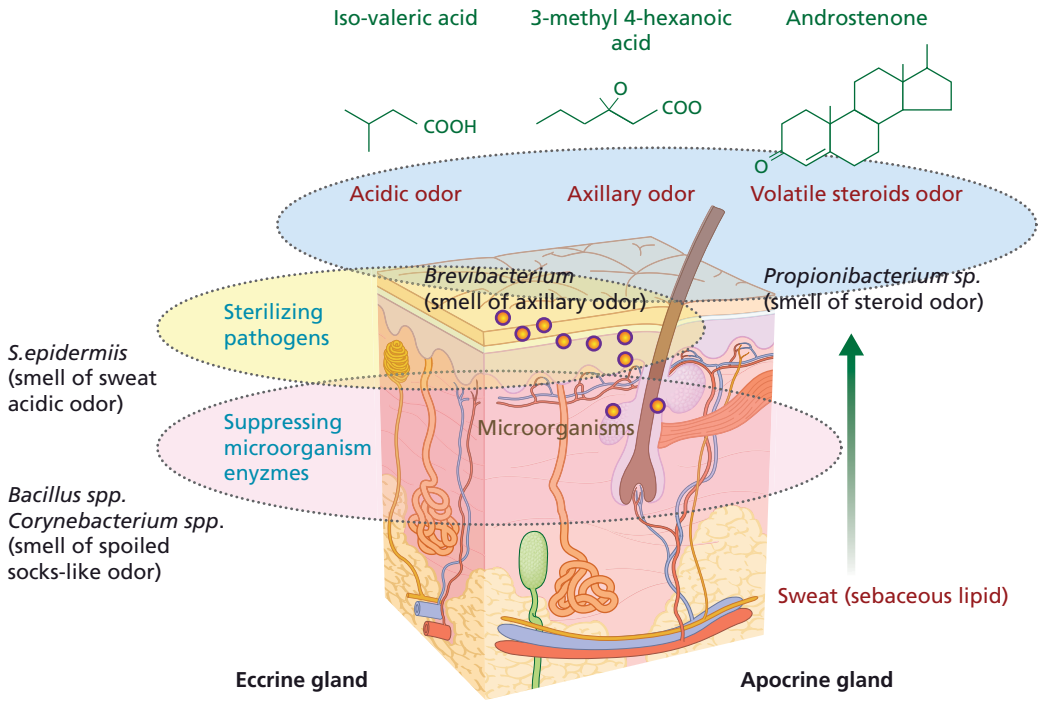

Figure 20.3 Sweat metabolism cycle.

glands to secrete fluid on to the surface of skin, where it then cools the body as it evaporates. The composition of the eccrine gland secretion is about 55–60% fluid, mostly water with various salts (Primarily: sodium chloride, potassium chloride) and various electrolytic components (ammonia, calcium, copper, lactic acid, potassium, and phosphorus). The warmth and limited air flow is conducive to allowing for rapid decomposition of organic matter made up of primarily low molecular weight volatile fatty acids (Figure 20.3). These fatty acids and the steroidal compounds produce the recognizable body odors.

The apocrine glands are triggered by emotions. These glands are dormant until puberty, at which time they start to secrete. Apocrine glands secrete a fatty substance. When under emotional stress, the wall of the tubule glands contract to push the fatty exudates to the surface of skin where bacterial flora begin breaking it down.

In a regulatory monograph [2] the FDA, through the Food Drug and Cosmetic Act, defines antiperspirants as an over-the-counter (OTC) drug when applied topically to reduce production of underarm sweat (perspiration). They are considered drugs because they can affect the function of the body by reducing the amount of sweat that reaches the skin surface. In the USA, OTC drugs are subjected to monograph rules, which define standards and requirements, premarket approval process, acceptable actives, and allowable formulation percentages of actives. Other countries' regulations vary in content and scope. Some countries consider antiperspirants as cosmetics and not affecting the biologic physiology of the body; as such they are not held to the same strict standards as in the USA. As an example, Canada has recently (2008) ruled that antiperspirants will longer be considered a drug; use of them now only needing to comply with cosmetic regulations.

Wetness and odor control and testing

The consumer typically confuses what antiperspirants and deodorants do, mostly caused by a misunderstanding of marketing claims and product positioning. For the most part, antiperspirants are based on aluminum-based cationic salt chloride complexes (as well as complexes with zirconium acid salts) and are referred to as "actives" on back label of consumer antiperspirant products. There are numerous types of antiperspirant actives listed in the FDA monograph as well as in the US Pharmacopia (USP) [3]. Antiperspirant actives are responsible for blocking sweat expulsion through the formation of temporary plugs within the sweat duct, thus stopping or slowing down the flow of sweat to the surface of the eccrine gland.

A theory to wetness control that has been accepted over the years is that the hydrated aluminum or aluminum–zirconium cationic salt chloride is transported to the eccrine gland, interacting with the protein contained within the gland. In this basic protein environment, the antiperspirant active is reduced, producing a gelatinous proteinaceous plug. By plugging the gland, sweat is prohibited from transporting to the surface, causing osmotic pressure. Eventually, this plug is pushed out of the eccrine gland and the gland is

allowed to operate again in a normal fashion. This can take 14–21 days for all the eccrine gland, to begin firing; known as a wash-out period.

Without going into detail, one can describe how antiperspirants are tested for their Wetness Inhibiting Performance ("WIP"™)[2] effectiveness. The FDA prescribes a methodology for testing the effectiveness of an antiperspirant by having participants tested in a controlled environment – 30–40% relative humidity at approximately 100 °C. Sweat is continuously collected during 20-minute intervals and reported as the production or percentage change in production over the average of two 20-minute collection periods. To be accepted as a participant one must exceed production of 100 mg collected sweat per 20-minute period and should not exceed more than 600 mg difference between the highest and lowest sweat production within the test population. The results of testing need to meet a minimum of 20% sweat reduction in 50% of the test population in order to be considered an antiperspirant.

Deodorants cover odor through a variety of mechanisms, which include the neutralization or counteracting of odoriferous axilla odor through the retardation of the odor development, or the reduction in perception of odor through masking of the odor. Masking is basically accomplished via use of fragrances and other volatile components. Neutralization is the chemical reaction to modify low molecular weight fatty acids that are excreted from the apocrine gland. One type of neutralization agent is antimicrobials that disrupt cell barrier viability causing the bacterial microbes to perish (triclosan is one popular example). Deodorants are designed to minimize underarm axilla odor, not to reduce or eliminate perspiration. So, deodorants are best for those people who do not have a problem with sweating yet want to feel fresh and odor free. It is important to note that deodorants have no antiperspirant physiologic activity, but antiperspirants can function both as antiperspirants and deodorants; thus, consumers needing odor and wetness control will require the use of antiperspirants to achieve their needs.

Chemistry and formulation of antiperspirants

It is important to have some understanding of the chemistry of antiperspirants to gain a better appreciation of their physiologic action in the axilla mantle. Antiperspirants are divided into two categories of functional aluminum-based and zirconium-based actives (typically: aluminum chlorohydrate, aluminum zirconium tetrachlorohydrex-GLY, aluminum zirconium trichlorohydrex-GLY, or aluminum chloride) plus an inactive formula matrix for consumer acceptable aesthetics.

The basic building block of antiperspirant actives is based on aluminum chemistry in which elemental aluminum is reduced in an acidic medium to produce what is traditionally known as aluminum chlorohydrate (ACH) with an atomic ratio of 2 : 1 aluminum to chloride. These inorganic cationic polymer salts are classified as octahedral complexes of a basic aluminum hydroxide, stabilized with an anionic chloride to maintain their water solubility. Within the monograph boundaries [2], the atomic ratio of aluminum to chloride can range from 2 : 1 to 1 : 1 within three different segmentations (aluminum chlorohydrate, aluminum sesquichlorohydrate, and aluminum dichlorohydrate).

Antiperspirant actives can also be complexed with hydrated acidic zirconium cationic salts of chloride to make what is traditionally known as aluminum zirconium chlorohydrate (ZAG or AZG). Like ACHs, AZGs can have various ratios of atomic aluminum to zirconium of 2 : 1 to 10 : 1 and atomic total metals to chloride of 0.9 : 1 to 2.0 : 1. These AZG complexes can be buffered with glycine (an amino acid) to stabilize the complex and mitigate the acidic harshness which could result when applied to underarm axilla.

There is a growing interest in aluminum-free odor and wetness controlling products. One product that has emerged is based on a natural stone "crystal." "Crystal" products are made from a mineral known as potassium alum, also known as potassium aluminum sulfate and contain aluminum. Unlike aluminum salts used in antiperspirants, alum does not prohibit sweating; it only helps control the growth of bacteria that can cause an underarm odor.

Delivery systems

The formulation matrix delivery system is the key to effectiveness of antiperspirant active performance and acceptable consumer application. The most common delivery systems are roll-ons (either aqueous or cyclosiloxane suspensions), aerosol (hydrocarbon propellant suspensions), extrudable clear gels (water-in-cyclosiloxane emulsions), extrudable opaque soft solids (anhydrous cyclosiloxane suspension pastes), or sticks (anhydrous cyclomethicone suspension solids) (Figure 20.4). Within each form there are typical inactive ingredients that support a stable formula with consumer-acceptable esthetics so as not to interfere with the WIP™ delivery of the antiperspirant active.

Although this chapter does not focus on details of formulation development, this subject can be researched in more detail in the literature [4,5]. In general, aqueous-based hydrous formulas (mostly based on roll-on and clear gel delivery systems) will have some type of emulsifier or stabilizing agent. In the case of aqueous roll-ons, they tend to

[2]Trademarked 2008 and property of Eric Abrutyn, TPC2 Advisors Ltd., Inc., Republic of Panama Corporation.

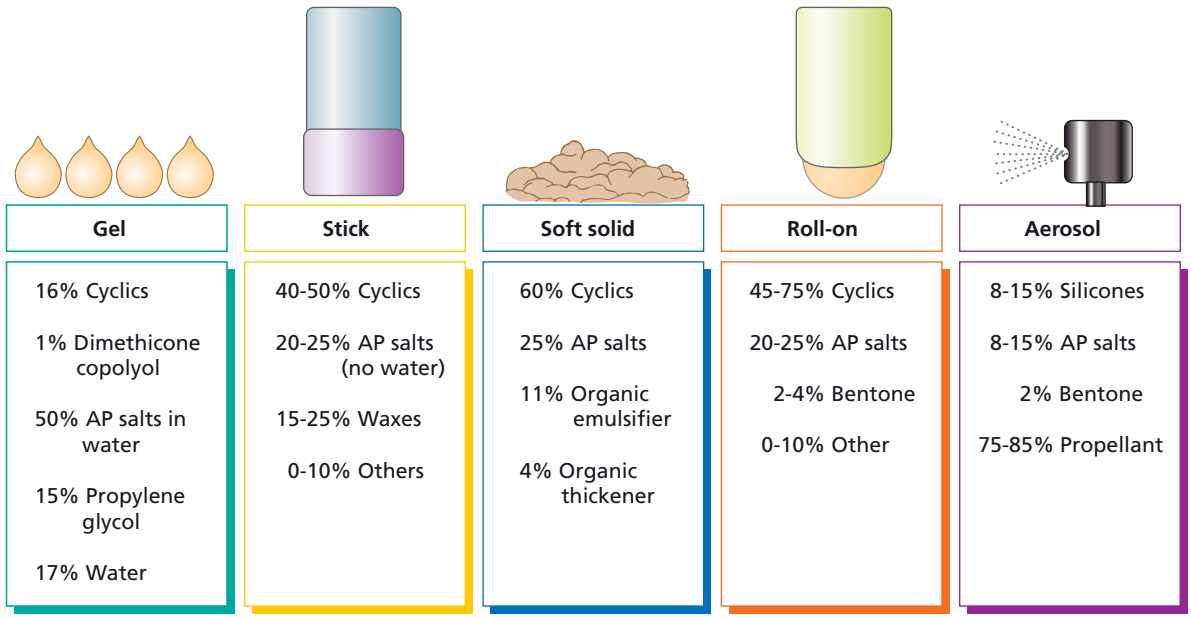

Figure 20.4 Antiperspirant formula matrix delivery systems.

be Polyethylene Glycol (PEG) or Polypropylene Glycol (PPG) ethoxylated alcohols (INCI e.g.: PEG-2, PEG-20) and for clear gel emulsions they are based on PEG and PPG alkoxylated functional siloxanes (INCI e.g.: PEG/PPG-18/18 Dimethicone Copolymer). Anhydrous-based formulas (typically: solid sticks, some types of roll-ons, extrudable creams) include cyclosiloxane (preferably Cyclopentasiloxane) for transient solvent delivery of the active and its eventual evaporation to leave no residue on the skin, solidification agent (INCI e.g.: Stearyl Alcohol, Hydrogenated Castor Oil, and miscellaneous fatty acid ester wax), and dispersing agent (INCI e.g.: PPG-14 Butyl Ether). Most antiperspirant formulas include other ingredients for cosmetic purposes, such as fragrance, antioxidants (BHT – Butylated Hydroxytoluene), chelating agents (Disodium EDTA – Disodium Edetate), soft feel powders (Talc, Corn Starch, and Corn Starch Modified), and emollients and/or moisturizers (petrolatum, mineral oil, fatty acid esters, non-volatile hydrocarbons). These ingredients have been used in the industry for well over 25 years with accepted safety profiles; reviewed by Cosmetic Ingredient Review (http://www.cir-safety.org/) and other governmental or medical agencies.

Dermatologic concerns

Each manufacturer of antiperspirants keeps a thorough record of adverse affects as reported by the consumer. For the most part, there is a low incident of adverse affects when the product is use as prescribed. Issues tend to revolve around skin irritation and sensitization. These adverse affects are reversible with cessation of use. Irritation can be brought about for a number of reasons, but most often by application on broken skin (e.g. from shaving) or sensitivity to the fragrance or one of the metallic components of the antiperspirant active. Switching brands or fragrances types is one remedy to alleviate adverse affects. In some cases a person is so sensitive to an antiperspirant active that he or she can no longer use a product containing an aluminum-based antiperspirant.

Health concerns regarding antiperspirants have been discussed in the literature over the last 40–50 years and mostly relate to breast cancer or Alzheimer disease. According to the Alzheimer's Association (http://www.alz.org/index.asp), the linkage of aluminum and Alzheimer disease is most likely linked to a single study in the 1960s where an abnormally high concentration of aluminum was observed in the brains of some Alzheimer patients. However, "After several decades of research," reports the Alzheimer's Association, "scientists have been unable to replicate the original 1960s study." In fact, there is still no scientific correlation on the cause and effect relationship for contracting Alzheimer disease. The research community is generally convinced that aluminum is not a key risk factor in developing Alzheimer disease. Public health bodies sharing this conviction include the World Health Organization, the US National Institutes of Health, the US Environmental Protection Agency, and Health Canada.

According to the National Cancer Institute (NCI) and the American Cancer Society, rumors connecting antiperspirant use and breast cancer are largely unsubstantiated by scientific research. The rumors suggest that antiperspirants prevent a person from sweating out toxins and that this helps the spread of cancer-causing toxins via the lymph

nodes. The NCI discusses two studies that address the breast cancer rumor. A 2002 study of over 800 patients at the Fred Hutchinson Cancer Research Institute found no link between breast cancer and the use of antiperspirant and/or deodorant [6]; and a study of 437 cancer patients, published in 2003 in the *European Journal of Cancer Prevention*, found no correlation between earlier diagnosis of breast cancer and antiperspirant and/or deodorant use [7]. The NCI's analysis of the second study was that it "Does not demonstrate a conclusive link between these underarm hygiene habits and breast cancer. Additional research is needed to investigate this relationship and other factors that may be involved."

Through the evaluation of these and other independent studies, it can be concluded that there is no existing scientific or medical evidence linking the use of underarm products to the development of breast cancer. The FDA (Food & Drug Administration), the Mayo Clinic, the American Cancer Society, and the Personal Care Products Council (formerly Cosmetic, Toiletry, and Fragrance Association) have come to a similar conclusion.

Sweating is necessary to control body temperature, especially during times of exercise and warm or hot surroundings. In a small portion of the population the sympathetic nervous system can go awry, affecting the complex biologic mechanism of perspiration, resulting in either excessive perspiration (hyperhidrosis) or little or no perspiration (anhidrosis). Currently, there are no known cures for hyperhidrosis but there are a number of treatment options: injectable treatment such as botulinum toxin type A (Botox), topical agents such as prescribed antiperspirants, oral medications, and surgery.

Based on information from the International Hyperhidrosis Society, over 87% of people with hyperhidrosis say that OTC antiperspirants do not provide sufficient relief. Thus, it is important for the medical community to understand the other options available to treat excessive sweating. Botox, a drug that has been approved for use as an injectable treatment in the axilla area, works to interrupt the chemical messages (anticholinergic) released by nerve endings to signal the start of sweat production. It is important to understand how to administer Botox in a manner that will not cause medical issues, thus only a trained practitioner should administer treatment. Unfortunately, Botox is not a permanent solution, and patients require repeat injections every 6–8 months to maintain benefits.

There are other options for treating excessive sweating, but none have been demonstrated to be either safe or effective for use by consumers. Most systemic medications, in particular anticholinergics, reduce sweating but the dose required to control sweating can cause significant adverse effects (e.g. dizziness), thus limiting the medications' effectiveness. Iontophoresis is a simple and well-tolerated method for the treatment of hyperhidrosis without long-term adverse effects; however, long-term maintenance treatment is required to keep patient's symptom free. Psychotherapy has been beneficial in a small number of cases.

Strengths and weakness of antiperspirants

Based on all the information known about antiperspirants one would surmise there are few weaknesses regarding the use of them. Basically, they serve the purpose of reducing the discomfort and potential observation of underarm wetness, and can lead to reduced underarm offensive odors. Except in the case of hyperhidrosis, antiperspirants serve to provide cosmetic esthetics and social acceptance. It is important to note that, even if used twice a day, antiperspirants do not completely stop axilla sweating, but provide a significant reduction in the amount of sweating produced in the axilla. With almost 70 years of use for antiperspirant actives, there is almost no association with adverse affects when properly used in the underarm area. So, the risk–benefit is minimal and is balanced by the ability to maintain a more comfortable and socially appealing state.

Conclusions

Because they are regulated in the USA and other countries as drugs, it is foreseen that introduction of new antiperspirant actives will be restricted. To introduce new antiperspirant actives, one would have to go through an extensive New Drug Application process, requiring costly studies on safety and effectiveness. Aside from the introduction of new antiperspirant drugs, dermatologists need to continue monitoring the introduction of unregulated new ingredients that would be included in existing or new formula matrices.

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Chapter 21: Blade shaving

Keith Ertel[1] and Gillian McFeat[2]

[1] Procter & Gamble Co, Cincinnati, OH, USA

[2] Gillette, Reading Innovation Centre, Reading, UK

BASIC CONCEPTS

- Hair removal practices have their roots in antiquity. While modern global attitudes towards hair removal vary, consumers around the world use blade shaving as a method to effect hair removal.
- Modern blades and razors are the product of extensive research and technologically advanced manufacturing procedures; these combine to provide the user with an optimum shaving experience.
- Effective shaving involves three steps: preparation, including skin cleansing and hair hydrating; hair removal, including the use of an appropriate shaving preparation; and post-shave skin care, including moisturizer application.

Introduction

Like many personal care practices, the roots of shaving lie in the prehistoric past. Hair removal for our cave dwelling ancestors was probably more about function than esthetics; hair could provide an additional handle for an adversary to grab during battle, it collected dirt and food, and provided a home to insects and parasites. Flint blades possibly dating as far back as 30 000 BC are some of the earliest examples of shaving implements. Archaeologic evidence shows that materials such as horn, clamshell, or shark teeth were used to remove hair by scraping. Pulling or singeing the hair, while somewhat more painful, were also methods used to effect hair removal.

Attitudes towards hair became more varied in ancient times. The Egyptian aristocracy shaved not only their faces, but also their bodies. The Ancient Greeks viewed a beard as a sign of virility but Alexander the Great, who is said to have been obsessed with shaving, popularized the practice among Greek males. Greek women also shaved; a body free from hair was viewed as the ideal of beauty in Greek society. Shaving was viewed as a sign of degeneracy in early Roman society, but an influx of clean-shaven foreigners gradually changed this attitude. For affluent Romans shaving was performed by a skilled servant or at a barbershop, which was popularized in Ancient Rome as a place of grooming and socializing. Shaving implements at this time were generally made from metals such as copper, gold, or iron.

The barbershop took on an expanded role in the Middle Ages. In these shops barbers provided grooming services and routinely performed other duties such as bloodletting and minor surgical and dental procedures. Shaving injuries were common and the striped pole that is today associated with barbershops has its origin in these times, its red and white stripes symbolizing blood and the bandages that were used to cover the wound, respectively.

The Industrial Revolution heralded a number of advancements in shaving technology. The straight razor was first introduced in Sheffield, England and became popular worldwide as a tool for facial shaving. While an improvement over earlier shaving implements, the straight razor dulled easily, required regular sharpening or stropping, and a high skill level, and shaving injuries were still a problem, which earned it the nickname of "cutthroat razor." Many credit Jean Jacques Perret with inventing the safety razor in 1762. His device, which he apparently did not patent, consisted of a guard that enclosed all but a small portion of the blade. Variations on the design followed from other inventors, many using comb-like structures to limit blade contact with the skin. The Kampfe brothers filed a patent in 1880 for a razor, marketed as the Star Safety Razor that used a "hoe" design in which the handle was mounted perpendicular to the blade housing. The blade, essentially a shortened straight razor, was held in place by metal clips. While generally successful, the blade in the Star Safety Razor still required stropping before each use.

In 1904, King C. Gillette introduced the real breakthrough that brought shaving to the masses. Unlike its predecessors, the Gillette Safety Razor used an inexpensive, disposable blade that was replaced by the user when it became dull. The new razor quickly gained popularity because of a variety of promotional efforts, including a "loss leader" marketing model pioneered by Gillette.

Shaving was not only promoted to males. The practice of shaving among females was prompted by the May 1915

Cosmetic Dermatology: Products and Procedures. Edited by Z.D. Draelos.

issue of *Harper's Bazaar* magazine that featured a picture of a female model wearing a sleeveless evening gown and sporting hairless axillae. The Wilkinson Sword Company built on the idea by running a series of advertisements targeting women in the 1920s to promote the idea that underarm hair was not only unhygienic, but was also unfeminine. Sales of razor blades doubled over the next few years.

Razor developments during the next several decades were primarily limited to improvements in single blade technology, including the switch from carbon steel to stainless steel blade material in the 1960s pioneered by Wilkinson Sword. This prevented corrosion, thus increasing blade life. The next major change occurred in the 1971 with the introduction of the Trac II, the first multiblade razor. Innovation has continued along this track and today consumers can choose from a variety of razor models having multiple blades contained in a disposable cartridge, with specialized designs available to meet the shaving needs of both sexes. The relatively simple appearance of these devices belies their sophistication; they are the product of years of development and technically advanced manufacturing processes.

Of course, not all shaving is done with a blade. Electric razors remove hair without drawing a blade across the skin. There are two basic types of electric razors, both relying on a scissor action to cut hairs using either an oscillatory or circular motion. When the razor is pressed against skin the hairs are forced up into holes in the foil and held in place while the blade moves against the foil to cut the trapped hairs. Colonel Jacob Schick patented the first electric razor in 1928. Electric razors were for many decades confined to use on dry skin, but some modern battery-powered razors are designed for use in wet environments, including the shower.

Hair biology basics

Much of the hair targeted for removal by shaving or other means is terminal hair (i.e. hair that is generally longer, thicker, and more darkly pigmented than vellus hair). In prepubescent males and females this hair is found primarily on the head and eyebrow regions, but with the onset of puberty terminal hair begins to appear on areas of the body with androgen-sensitive skin, including the face, axillae, and pubic region. Further, vellus hairs on some parts of the body, such as the beard area, may convert to terminal hairs under hormonal influence.

The pilosebaceous unit

A pilosebaceous unit comprises the hair follicle, the hair shaft, the sebaceous gland, and the arrector pili muscle. The hair follicle is the unit responsible for hair production. Hair growth is cyclical, and depending on the stage of hair growth, the follicle extends to a depth as shallow as the upper dermis to as deep as the subcutaneous tissue during the active growth phase.

The hair shaft is the product of matrix cells in the hair bulb, a structure located at the base of the follicle. The hair shaft is made up primarily of keratins and binding material with a small amount of water. A terminal hair shaft comprises three concentric layers. Outermost is the cuticle, a layer of cells that on the external hair are flattened and overlapping. The cuticle serves a protective function for external hair, regulates the water content of the hair fiber, and is responsible for much of the shine that is associated with healthy hair. The cortex lies inside the cuticle and is composed of longitudinal keratin strands and melanin. This layer represents the majority of the hair shaft and is responsible for many of its structural qualities (e.g. elasticity and curl). The medulla is the inner most layer found in some terminal hair-shafts, made up of large loosely connected cells which contain keratin. Large intracellular and intercellular air spaces in the medulla to some extent determine the sheen and colour tones of the hair.

Each hair follicle is associated with a sebaceous gland. This gland lies in the dermis and produces sebum, a lipophilic material composed of wax monoesters, triglycerides, free fatty acids, and squalene. Sebum empties into the follicle lumen and provides a natural conditioner for the forming and already extruded hair. The arrector pili is a microscopic band of smooth muscle tissue that connects the follicle to the dermis. In certain body sites, when stimulated the arrector pili contracts and causes the external hair to stand more erect, resulting in the appearance of goose bumps.

Hair growth cycle

Hair growth is not a continuous process but occurs over a cycle that is conveniently divided into three stages; at any given time hairs on a given body site are at various points in this cycle. The dermal papilla orchestrates the hair growth cycle. Anagen is the phase of hair follicle regrowth and hair generation. During this stage the hair follicle grows downward into the dermis and epidermal cells that surround the dermal papilla undergo rapid division. As new cells form they push the older cells upward. The number of hairs in anagen varies according to body site. At any given time approximately 80% of scalp hairs are in anagen. This is lower for beard and moustache hairs (around 70%) and only 20–30% for the legs and axillae. The length of the anagen phase also varies; on the scalp anagen typically lasts from 3 to 6 years, in the beard area this is closer to 1 year and in the moustache area anagen lasts from 4 to 14 weeks. Anagen is typically 16 weeks for the legs and axillae. The time in anagen determines the length of the hair produced [1].

Anagen is followed by catagen, a transitional phase in the hair growth cycle that sets the stage for production of a new follicle. In catagen the existing follicle goes through

controlled involution, with apoptosis of the majority of follicular keratinocytes and some follicular melanocytes. The bulb and suprabulbar regions are lost and the follicle moves upward, being no deeper than the upper dermis at phase end. The dermal papilla becomes more compact and moves upward to rest beneath the hair follicle bulge. On the scalp catagen lasts 14–21 days.

Telogen is a phase of follicular quiescence that follows catagen. The final cells synthesized during the previous cycle are dumped at the end of the hair shaft to form a "club" that holds the now non-living hair in place. These hairs are lost by physical action (e.g. combing) or are pushed out by the new hair that grows during the next anagen phase. The percentage of follicles in telogen also varies by body site (e.g. 5–15% of scalp follicles are normally in telogen whereas 30% of follicles on the beard area are normally in telogen and 70–80% of leg and axillae hairs). Telogen typically lasts for 2–3 months, although this is slightly longer for leg hairs [1].

Properties of hair – impact on shaving

The beard area of an adult male contains between 6000 and 25 000 hair fibers and beard growth rate has been reported in the literature to be 0.27 mm per 24 hours, although this can vary between individuals [2]. There are two types of hair fibers found in the beard area. Fine, non-pigmented vellus hairs are distributed amongst the coarser terminal hairs. While the literature abounds in publications on the properties of scalp hair, studies of beard hair are relatively scarce.

Tolgyesi *et al.* [3] published the findings of a comparative study of beard and scalp terminal hair with respect to morphologic, physical, and chemical characteristics. Scalp fibers were reported to have half the number of cuticle layers compared to beard hairs from the same subject (10–13 in facial hair, 5–7 in scalp hair). Scalp fibers also had smaller cross-sectional areas (approximately half the area) and were less variable in shape than beard hairs, which exhibited asymmetrical, oblong, and trilobal shapes. These differences can be seen in Figure 21.1. Thozur *et al.* [4] further showed considerable variations in beard hair follicle shape and diameter within and between individuals. A number of factors contribute to this variation including anatomical location, ethnicity, age, and environmental factors.

The structural properties of the hair impact shaving. The force required to cut a hair increases with increasing fiber cross-sectional area [5]. Thus, it requires more force to cut a larger fiber. Indeed, it requires almost three times the force to cut a beard hair than a scalp or leg hair. One important property of hair is that the force required to cut it can be greatly reduced by hydrating the hair. Hydration causes the hair to become significantly softer and much easier to cut so that it offers less resistance to the blade and minimizes any discomfort.

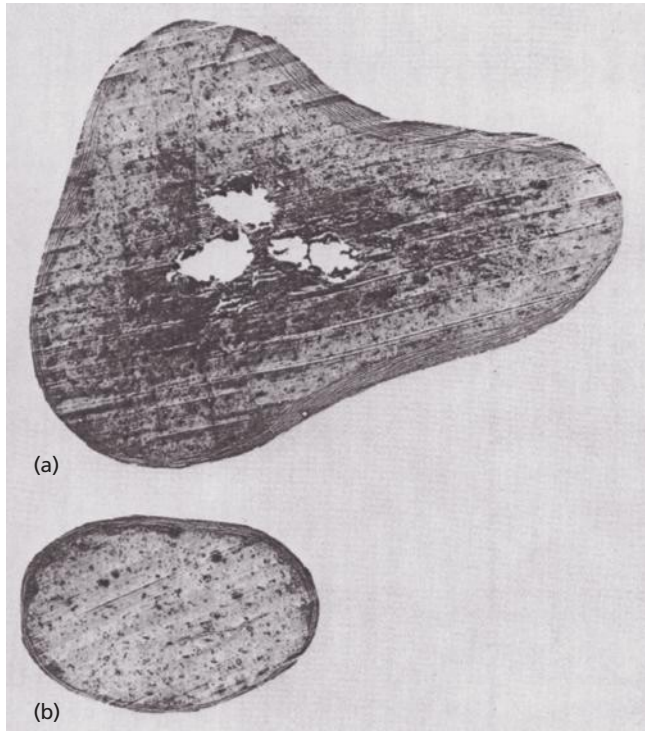


Figure 21.1 Optical micrographs of hair cross-sections taken from the beard (a) and scalp (b) area of the same subject. Beard fibers have a greater cross sectional area and more cuticle layers.

The human hair follicle and the surrounding skin are richly innervated. In particular, the terminal hairs of the human skin are supplied with several types of nerve endings most of which are sensory in nature. It is hypothesized that discomfort associated with shaving (during shaving or post-shave) is a result of localized skin displacement and/or the rotation and extension of the beard fiber in its follicle. The current neurologic literature clearly demonstrates that such local cutaneous distortions bring about the release of various chemical communicators (e.g. histamine, prostaglandins, bradykinins) that heighten the sensitivity of the response of pain-mediating nerve endings for a period of time [6]. The contribution to shaving comfort and irritation remains to be elucidated.

Shaving can also cause irritation by physical damage. There is evidence to suggest that shaving irritation involves the removal of irregular elevations of the skin by the razor blade, particularly around follicular openings [7,8].

The topography of the skin is highly variable and combined with the presence of hairs this creates a very irregular terrain over which an incredibly sharp blade traverses (Figure 21.2). This can result in irritation, generally characterized in this context by the presence of attributes such as nicks or cuts, redness, razor burn, sting, or dryness. In order to achieve a close and comfortable shave with minimal irritation it is essential to use a good quality, sharp blade and

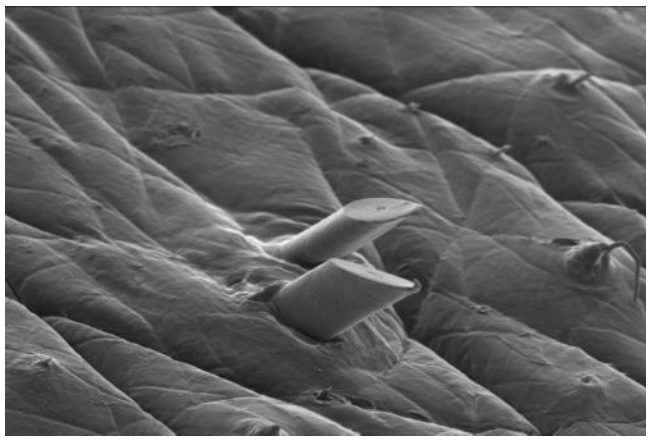


Figure 21.2 A scanning electron micrograph of a replica of an area of cheek on a male face. The topography of the skin is highly variable and combined with the presence of hairs this creates a very irregular terrain over which an incredibly sharp blade traverses.

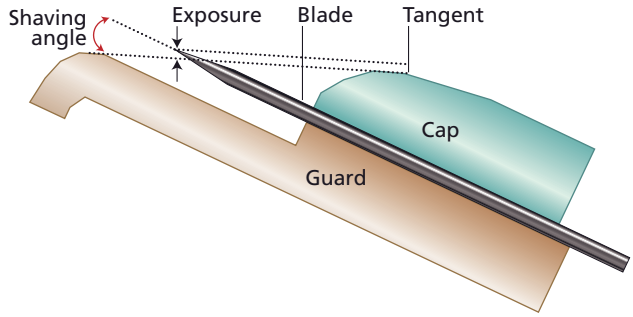


Figure 21.3 Cross-section of a double-edge razor showing exposure geometry.

adopt a shave care regimen designed to remove as much hair as possible while inflicting minimal damage to the underlying skin.

Shaving and the razor explored

Since the invention of the safety razor, consumer product industries have invested a considerable amount of time, money, and expertise in improving the design of the razor and blade in order to provide a closer, more comfortable, and safer shave.

To date, few reports have been available in the literature detailing the shaving process and the mechanisms involved. The following section aims to provide an overview of the razor and the complex mechanisms by which the blade cuts the beard hair and interacts with the underlying skin.

Evolution of the system razor

With a system razor, only the cartridge containing the blades is replaced, unlike a disposable razor which is thrown away in its entirety when blunt.

In the first double edge razor systems, the consumer had to position and tension a single blade within the handle. As a result, there was variability and inconsistency in how the blade interacted with the skin. In contrast, the advanced shaving systems of today are precisely assembled during manufacture.

Figure 21.3 shows a cross-section of a double edge razor with the key parameters of the cartridge geometry indicated. The shaving angle is the angle between the center plane of the blade and a plane tangent to the guard. The blade exposure is the amount by which the tip of the blade projects beyond the plane tangent to the cap and guard. Altering any of these parameters has both good and bad effects. For example, an increase in blade exposure brings the blades into closer contact with the underlying skin and hair, increasing the closeness of a shave at the expense of more nicks and cuts and discomfort. A reduction in the shaving angle improves comfort but reduces cutting efficiency. Consequently, all aspects of the double edge blade system were compromises and the user was able to adjust the razor to suit their individual preferences [9].

Modern systems have reduced the need to compromise and achieved the previously unattainable: improving closeness, safety, and comfort simultaneously. The improvement in closeness is attributed to, and exploits the mobility of the hairs within the follicle. Observation of the movement of hairs during shaving has shown that they are not cut through immediately upon contact with the blade; rather, they are carried along by the embedded blade tip, and effectively extended out of the follicle. This extension is primarily brought about by the distortion of the soft tissue between the hair root and the skin surface layers. Because of the viscoelastic nature of the tissue, once severed the hair rapidly retracts back into the follicle. If a second blade follows closely behind the first, it can engage the hair in the elevated state, cutting it further down the hair shaft, before it has time to fully withdraw into the follicle [9]. By having multiple blades, this process can be exploited to give a measurable improvement in closeness. It is therefore possible to use a lower blade exposure to achieve closeness while minimizing skin contact and thus the potential for nicks, cuts, and discomfort.

Simply adding more blades to razors is not a new idea (the first US patent for a 5-blade razor was filed in 1929, US1920711) and from the above it is clear that on its own this will not deliver a great shave. In addition to precisely controlling the razor geometry, it is essential that the underlying skin is carefully managed to ensure a safe and comfortable shave. Adding more blades improves closeness by virtue of hair extension and probability of cutting, but can also create drag and discomfort. The pressure exerted on the skin by the additional blades can cause the skin to bulge between

the inter blade span. By spacing the blades closer together, both the drag and skin bulge are reduced and a more uniform stress is placed on the skin leading to a safer, more comfortable shave (Figure 21.4).

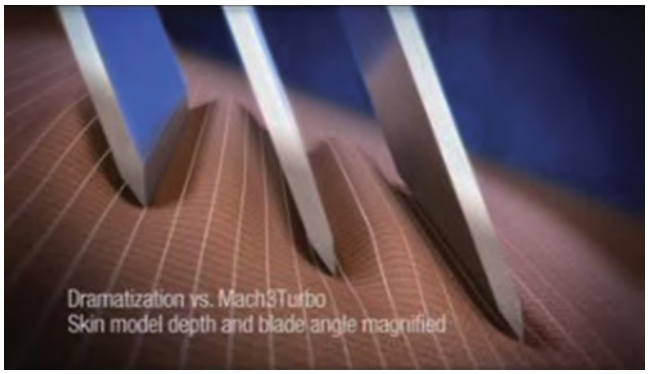
Manipulating these parameters can greatly alter the characteristics of a shave; consequently cartridge geometry and blade spacing are carefully controlled and set during manufacturing using specifications determined through extensive research. This ensures that the consumer receives a targeted and consistent shave with the optimum blade–skin contact.

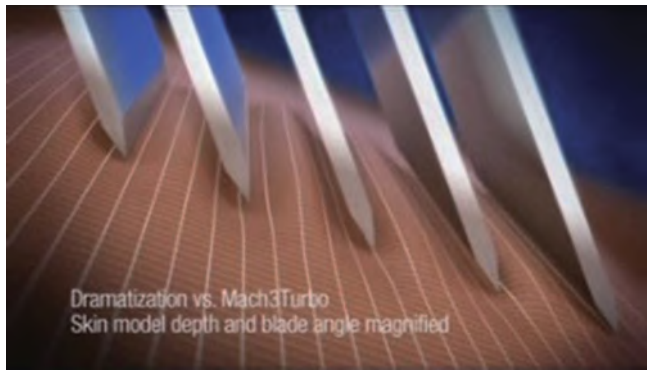
Cutting edge technology

A further critical component of the shaving process, and central to a great shave, is the razor blade edge. The narrower the blade edge the more easily it can cut through a hair, leading to a closer and more comfortable shave. However, if the blade is too narrow it can collapse under the cutting force. Thus, the industry strives to produce the thinnest blade edge possible while retaining blade edge strength. This is typically achieved by treating a stainless steel substrate with thin film coatings such as diamond-like carbon to enhance edge strength or platinum-chromium to enhance corrosion resistance. The blades are further coated in a telomer like material to create a low friction cutting surface. This greatly reduces the force required to cut hair, minimizing hair "pulling," providing additional comfort.

Additional key components of a modern razor are shown in Figure 21.5. First introduced in 1985, lubricating strips are now found on most disposable and permanent system cartridges. The strips distribute water-soluble lubricant following each shaving stroke, resulting in a significant reduction in drag of the cartridge over the skin and allowing additional strokes to be taken comfortably even after most of the shaving preparation has been shaved off. The strips also allow the skin to release freely from the tension created

(a)





(b)

Figure 21.4 Multiple blade razors and skin management. Spacing 5 blades closer together (b), creates a shaving surface that helps spread shaving force for a safer, more comfortable shave.

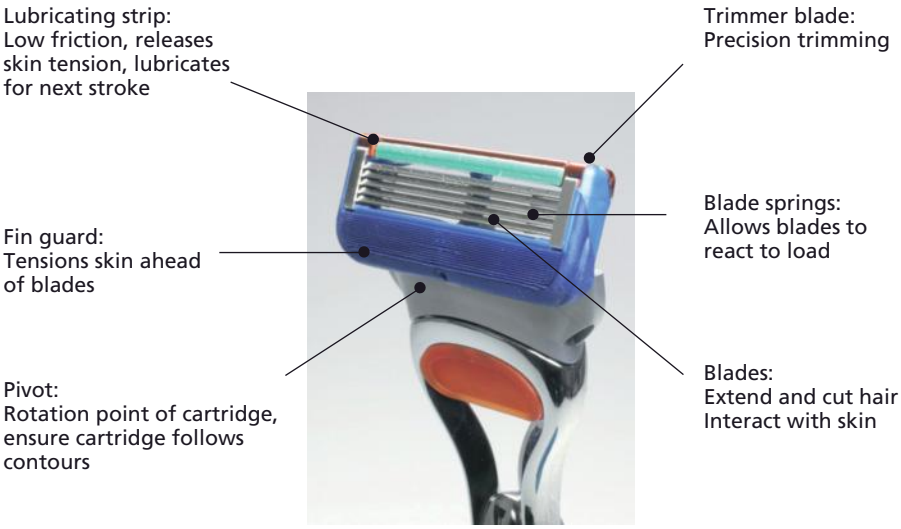


Figure 21.5 The key components of a razor and their functions.

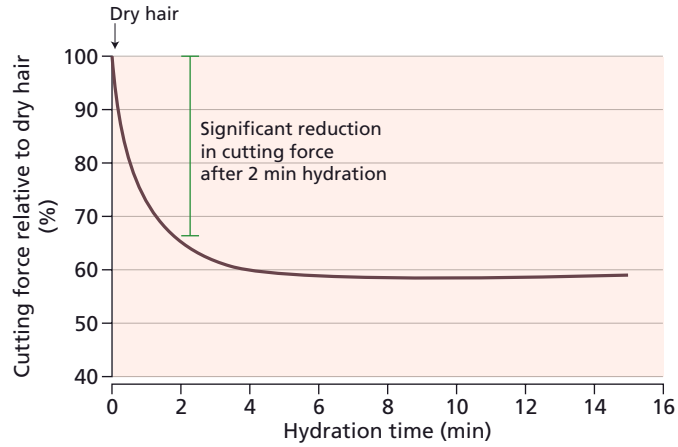


Figure 21.6 Effect of hydration time on force required to cut (beard) hair. The most significant reduction occurs over the first 2 minutes.

by the skin guard. The guard is typically comprised of soft, flexible microfins or rigid plastic which precede the blades. These microfins gently stretch the skin, causing beard hairs to spring upward so they can be cut more efficiently. Additional features include pivoting heads that allow the cartridge to follow the contours of the face and trimmer blades allow the shaver to get exact positioning of the blade for a closer, more precise shave. The recent introduction of oscillating wet shaving systems increases razor glide for improved comfort.

Such advances in blade edge and razor technology, coupled with an understanding of the needs of the consumer, have significantly enhanced the quality, closeness, safety, and comfort of the shave. This is most evident when combined with a shave care regimen designed to maximize hair removal and minimize skin damage.

The shaving process

Drawing a sharpened implement across the skin's surface has the potential to cause damage and dry shaving can result in the immediate appearance of uplifting skin cells and perturbation of stratum corneum barrier function, with an increase in dryness observed several days subsequent to the initial damage [10]. Body site will likely influence the response to this insult because the number of stratum corneum cell layers varies over the body surface, averaging 10 layers on the cheek or neck and 18 layers on the leg [11]. The potential for damage is compounded by non-uniform skin surface topography and the presence of hair (Figure 21.2), which when dry is relatively tough. A dry hair has about the same tensile strength as a copper wire of equivalent diameter.

A few simple steps can help prepare the skin and hair for an optimum shaving experience. First, the skin should be thoroughly cleansed. Cleansing removes surface soils that can interfere with the shaving process and also helps hydrate the hair. The latter is especially important and shaving during or after showering or bathing is ideal but short of this, the area to be shaved should be washed with a cleanser and warm water. In some situations applying a warm, wet towel or cloth to the skin for a few minutes before shaving may also help. Hair is mostly keratin, and keratin has a high affinity for water. Hydrating softens the hair to make it more pliable and easier to cut; the force required to cut a hair decreases dramatically as hydration increases (Figure 21.6). Short-term hydration will also improve the skin's elasticity [12], making it better able to deform and recover as the blade is drawn over its surface. However, more is not necessarily better; prolonged soaking can macerate skin and cause the surface to become uneven, making effective hair removal more difficult and increasing the risk of damaging the skin. Excessive soaking can also deplete the stratum corneum of substances such as natural moisturizing factor (NMF) that help it hold on to water [13], which can exacerbate any dryness induced by the shaving process.

A preparation such as a shaving gel or cream can also improve the shaving experience. A preparation serves several functions. The physical act of applying preparation to the skin can remove oils and dead skin cells from the surface and aid in the release of trapped hairs, with the potential to improve the efficiency of the cutting process. Shaving preparation formulas typically contain a high percentage of water, which provides an additional hydration source for the hair and skin. Finally, shaving preparations are usually based on surfactants and contain other ingredients such as oils or polymers. For reasons already noted hydrating hair and skin is important for the shaving process, but hydration increases the coefficient of friction for an object sliding across the skin's surface [14]. The surfactants, oils, and polymers in shave gels can reduce friction to improve razor glide, provide a cushion between the blade and skin, and improve cutting efficiency.

Table 21.1 Summary of some differences between males and females related to hair characteristics and blade shaving behaviors and attitudes.

	Male	Female
Onset of shaving behavior	Most males begin shaving between the ages of 14 and 15	Most females begin shaving between the ages of 11 and 13
Body areas shaved	Most male shaving occurs on the face and neck areas. The average male shaves an area of ~300 cm^2	Female shaving is focused on the leg and underarm areas. The average female shaves an area of ~2700 cm^2
Relative hair density	Higher hair density. On average the male face has 500 hair follicles per cm^2 [7]	Lower hair density. On average the leg and axillae have 60–65 hair follicles per cm^2 [7]
Hair growth pattern	Hair on the face tends to grow in multiple directions	Hair on the legs tends to grow in the same direction, but hair in the underarm area grows in multiple directions
Location where shaving occurs	Males tend to shave at the bathroom sink	Females tend to shave in the shower or bath
Attitudes towards shaving	Males tend to view shaving as a skill	Females tend to view shaving as a chore

Equipment and technique are also important for an optimum shaving experience. The razor should be in good condition with a sharp blade. A dull blade will not cut the hair cleanly and will pull the hair, increasing discomfort and the likelihood of nicks and cuts. Shaving in the direction of hair growth with a light pressure is recommended to reduce pulling, at least for the first few strokes. These preliminary strokes can be followed up with strokes against the grain if additional hair removal is needed. On the face, feeling the beard with the hand can help identify hair growing patterns and guide stroke direction. Skin on some areas of the body, such as the underarms, has a naturally uneven or very pliable surface. Pulling the skin taut on these areas during shaving can improve the efficiency of the hair removal process and reduce nicking or cutting. In all cases the razor should be rinsed often to keep the blade surface clean.

Some situations may require extra care during the shaving process. For example, pseudofolliculitis barbae (PFB) is a condition that affects individuals with very tightly curled hair, such as those who are of African descent. In PFB hairs may grow parallel to, rather than out from, the skin's surface and in some cases the tip of the hair curves back and grows into the surface of the skin, causing inflammation. Individuals prone to developing PFB should thoroughly hydrate the hair before shaving, liberally use a shaving preparation and if blade shaving, shave daily with a sharp razor.

Following the shave, skin should be thoroughly rinsed with water to remove all traces of shaving preparation, because these products are generally surfactant-based and leaving surfactant in contact with the skin can induce or exacerbate irritation. Rinsing with cool water can have a soothing effect on the skin. Applying a moisturizer can also have a soothing effect and will hydrate the skin to help prevent dryness. Moisturizers can also speed the barrier repair process and thus help to mitigate any stratum corneum damage that might result from shaving.

These steps apply generally to blade shaving needs for both sexes. However, there are differences between males and females in terms of hair characteristics and blade shaving behaviors and attitudes. As a result, razors for females are often designed to accommodate body specific needs. Some of these differences are summarized in Table 21.1.

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