TAB 3 **Excerpt of Comments from the SDA/CTFA Industry Coalition Regarding the Benefit and Efficacy of Consumer Antiseptic Bodywashes (75N-183H; C12, volume 1)**

Antimicrobial Bodywash

Bacteria are ubiquitous in the environment and are part of the normal flora of the skin (Noble, 1983). Antimicrobial bodywashes are used to control the numbers of bacteria where appropriate (Marzulli and Bruch, 1981). Because the organisms of potential concern are primarily Gram positive, the activity of antimicrobial agents used in antimicrobial bodywashes should be suitable for that use and so may be of limited spectrum. This will enable a proportion of the normal flora to remain. On the other hand, products such as surgical scrubs and preoperative skin preparations must have broad spectrum activity against a vast array of both resident and transient flora, as their role is microorganism control prior to invasive surgery.

Public Health Importance

Skin infections due to Gram positive organisms are recognized as a common and significant public health problem (Hay, 1993; Roth and James, 1989). These skin diseases are most commonly caused by staphylococci and streptococci. They include pustules, folliculitis, impetigo, furuncles, and infection of cuts and scrapes. In addition to the staphylococci and streptococci, other Gram positive bacteria such as *Corynebacterium minutissimum*, can cause contagious skin infections like erythrasma.

The American Society for Microbiology Manual of Clinical Microbiology (Isenberg and D'Amato, 1994) has identified approximately one hundred of the most frequently isolated skin organisms. It must be remembered that the vast majority of skin infections encountered by consumers are never cultured and that the clinic and home environments may be quite different.

According to data obtained from the National Disease and Therapeutic Index (NDTI), on average from 1992 to 1994 there were approximately two million diagnosis visits per year to dermatologists, pediatricians, and general or family practitioners and others for impetigo, pyoderma, and carbuncles/furuncles. Pediatricians made 38% of these diagnosis, dermatologists 10%, general or family practitioners 30%, and others 21%. Doctor visits by specialty are detailed below:

Doctor Visits (Thousands) by Specialty

Year	1992	1993	1994
Pediatrics	**902**	**681**	**743**
Impetigo	846	645	719
Carbuncle/Furuncle	33	25	18
Pyoderma	23	11	7
Family/General	**635**	**638**	**579**
Impetigo	406	445	385
Carbuncle/Furuncle	149	158	143
Pyoderma	80	36	51
Dermatology	**205**	**212**	**199**
Impetigo	91	119	96
Carbuncle/Furuncle	42	40	17
Pyoderma	72	54	87
Total Other Specialties	**304**	**473**	**470**

It has been estimated that up to 8% of visits to dermatology clinics are a result of some form of pyoderma (Aly and Maibach, 1988; Stern and Nelson, 1993). Skin related problems constitute about 6.8% of the visits to general pediatric clinics (Ben-Amitai and Askenazi, 1993). Of these, about half are cutaneous infections, some of which can lead to frequent recurrence and intrafamilial spread. A recent survey estimated that 5.5 million office visits per year are due to skin infections. In a survey of a pediatric dermatology clinic the second, third, and fifth most frequently diagnosed conditions were infectious diseases (Schachner et al., 1983). Of all diagnoses, 33.6% were infections or infestations, of which 29% were bacterial, 42% fungal, and 23.2% viral.

The occurrence of skin infections is highly correlated to geography and climate (Taplin et al., 1973). There is a higher frequency of infections in areas with high temperatures and humidity. The conditions found in the tropics or during the summer months are conducive to both fungal and bacterial infections. Age and personal hygiene can also significantly influence rates of infection; the higher frequency of impetigo among children is an example (Aly and Maibach, 1987).

Atopic dermatitis affects approximately 10-15% of the population. Clinical studies have shown that the skin flora of atopics is quantitatively and qualitatively different from the skin of the normal population (Lacour and Hauser, 1993). It has been reported that these patients have increased numbers of skin flora and a higher frequency of colonization with *Staphylococcus aureus*, not only on their skin, but also in their nares (Sampson, 1992). The skin of 95% of atopic patients (versus about 5% of normal controls) was found to be colonized with *S. aureus*. In the acute lesions and chronic plaques associated with this disease, the density of *S. aureus* was higher than in the unaffected skin (Lacour and Hauser, 1993). Due to the chronic presence of this organism, it is not surprising that patients with atopic dermatitis experience increased numbers of skin infections. In experimental staphylococcal infection there is a direct relationship between the numbers of staphylococci applied to normal skin and the likelihood that infection will occur (Noble, 1993).

Chronic, asymptomatic carriage of *S. aureus* in the nares occurs in 20 - 40% of the normal population (Williams and Mackie, 1993). It is known that nasal carriage of *S. aureus* can be correlated to higher rates of infection in individuals. This organism may be transferred from the nose to other skin sites. Many normal daily activities that result in minor cuts and scrapes have the potential to become contaminated with these transferred *S. aureus* and other organisms from environmental sources.

A survey of skin problems in the elderly (Beauregard and Gilchrest, 1987) identified skin infections in non-institutionalized patients ages 68 and up. It was strongly suggested that skin problems, including infections, were common. Also, bathing and shampooing were often substantially limited, adversely effecting personal hygiene.

Transmission of skin infections between family members is well-recognized. Kay (1962) reported from a study of families that staphylococcal infection in one family member later spread to other family members in half the cases, with the axilla and perineum, in addition to the nares, as potential sources of the organisms. In half of the cases another member of the patient's family was found to carry the infecting strain even if the patient was not a nasal carrier.

Impetigo can spread in families, Dillon (1968) found 497 cases of impetigo in 347 families indicating intrafamilial transmission. In another study (Ferrieri et al., 1972), the mean interval from index to secondary skin acquisition was 4.8 days and recovery of a serotype from normal skin was associated with a high risk (76%).

Zimakoff et al. (1988) pointed out the importance of reinfection on the transmission of staphylococcus within families and concluded that a residual effect is desirable to help prevent reacquisition of staphylococci that are shed into the household environment on sheets, towels, etc.

Children overwhelmingly constitute the population at greatest risk for bacterial skin infection, with those under nine years of age having the greatest incidence. The number of children worldwide with skin infections is estimated to be in the millions and constitutes a significant load on medical services (Taplin et al., 1973).

Recently, in the United States special occurrences affecting many households were shown to increase the incidence of skin infections. Quinn et al. (1994) reported on medical care of families affected by Hurricane Andrew in 1992. During the two weeks following the storm there were noted increases in pediatric dermatologic infections including impetigo, wound infections, and cellulitis.

Antimicrobial washes are used for whole body cleansing, to reduce odor-causing bacteria, and to help control bacteria that can cause skin infections. Ehrenkranz and Alfonso (1992) point out, "a pervasive misconception in infection control circles is that simple handwash reliably prevents hand transmission of transiently acquired bacteria...."

The breach or destruction of the skin defenses as a result of abrasions, cuts, burns, or the action of toxic chemicals inevitably leads to increased colonization of the area by microorganisms. Thus, the likelihood of infection from the reduced defense capacity is increased. However, less severe, and often barely detectable changes in the balance of the surface inhabitants of the skin can also increase the susceptibility to infection. These changes can be induced by alterations in host metabolism, and other factors that modify the surface environment even though they do not sever the epidermis (Selwyn, 1981).

The study of the role of transient skin organisms such as *Escherichia coli*, *Klebsiella pneumoniae*, *Shigella* sp., *Salmonella* sp. as well as resident *Staphylococcus aureus* in the transmission of clinical infection has been thoroughly documented (Larson, 1988; Rotter, 1990; Noble, 1993). The use of antimicrobial handwash products is directed primarily towards this function and has been discussed in the previous section.

The role of normal resident body flora has not received as much attention in the past. Only recently has there been a much greater appreciation of the role normal flora plays in infection. Although the normal microflora of the skin is a valuable defense mechanism, its occasional failures are readily apparent in primary pyoderma and the secondary infection of dermatoses, wounds, and burns. Superficial pyogenic skin infections range in importance from a simple nuisance to serious, and even fatal, medical problems (Duncan et al., 1969; Selwyn, 1981).

Washing with a non-antimicrobial wash product will help remove transient microorganisms from the skin. This is accomplished by the action of both mechanical scrubbing, and the surfactancy of the soap or detergent base. The routine use of bodywash products, either as bars, liquids, or shower gels, which contain an antimicrobial ingredient, can reduce and control the number of resident organisms which survive on the intact skin. They may also deposit a substantive active ingredient onto the stratum corneum which can help prevent the colonization of pathogenic organisms such as staphylococci (Aly and Maibach, 1981).

The cutaneous resident microflora is predominantly composed of coagulase negative species of *Staphylococcus*, streptococci, aerobic Gram positive non-spore forming bacilli, which are usually referred to as coryneform bacteria, and anaerobic *Propionibacterium*. The hair follicle is the site of the largest concentration of microorganisms. The numbers of these residents vary widely depending on the particular micro-environments present on the body surface. Skin infections due to Gram positive organisms are recognized as a common and significant public health problem (Noble, 1983).

Many normal daily activities that result in minor skin trauma have the potential to become contaminated with transferred *S. aureus* organisms. Specialized skin areas of the body, such as the vulva, can harbor *S. aureus*, and may be a foci of chronic staphylococcal infections, as well as play a role in cross-infection between individuals (Elsner and Maibach, 1990). The residual activity of an antimicrobial wash product is desirable in preventing the transmission and reinfection from staphylococci (Zimakoff, 1988).

Because of the normal colonization of the skin with coagulase negative staphylococci, it is difficult to be certain that small localized lesions, such as those found in folliculitis, are due to those organisms. There are a number of other infections, such as cellulitis and otitis media, which have been attributed to the coagulase negative staphylococci (Noble, 1993; Feigen et al., 1973).

Skin infection with streptococci covers a range from simple colonization to primary and secondary infections. The skin provides an important portal of entry for systemic infection by these organisms. Minor trauma to the skin not prompting specific first aid attention, such as trivial cuts, abrasions, and scratches may allow streptococci to initiate infection (Noble, 1993). Staphylococci and streptococci are often found in mixed cultures from pyoderma lesions, and there is still controversy over which is the more important pathogen.

Most streptococcal skin infections occur among children and their contacts, under conditions of overcrowding and poor hygiene, particularly in warm and humid parts of the world. Even in developed parts of the world, streptococci are commonly isolated from many clinical specimens. This is likely due to many factors including the common asymptomatic carriage of organisms, the minor nature of most infections which are left untreated, and the opportunities for bacterial transmission that exist as people work, live, and play together.

Erythrasma is a common superficial cutaneous infection, usually asymptomatic, caused by *Corynebacterium minutissimum* which affects the axillae, groin, and toe webs (Feingold et al., 1989; Taber et al., 1969). These coryneform bacteria are common resident flora of the normal skin. The factors responsible for transforming this normal skin inhabitant into a form that produces keratinolytic enzymes which invade the stratum corneum are unknown (Noble, 1993).

Gram negative bacilli are comparatively rare on normal skin. Apart from the hands, which may be temporarily colonized by a variety of bacilli, the majority of organisms cultured from skin are probably transients or contaminants. *Acinetobacter* is the only genus of Gram negative bacilli which is regularly found in significant numbers of individuals as a member of the normal body flora. Skin infection by *Acinetobacter* is rare, but cellulitis has been reported (Noble, 1993). This limits the need for the routine use of high activity, broad spectrum antimicrobial ingredients, such as chlorhexidine, for this type of product.

Antimicrobial wash products are used for whole body cleansing to reduce odor and help prevent minor skin infections. The efficacy of the ingredients used in antimicrobial washes against the types of organisms outlined has been well documented. The regular use of these products results in the deposition of a bacteriostatic residue, which can significantly reduce the carriage of these organisms on the skin, and play a role in the prevention of disease. Broad spectrum activity is less likely to be important in routine bodywashing, although it may be desirable in some specific instances.

Methods

Based on an understanding of the risks involved, the organisms of greatest significance, the population affected, and the products and frequency of use in this category, it is recommended that the following testing procedures and efficacy guidelines be used for antimicrobial bodywashes. Both *in vitro* and *in vivo* methods are proposed (Table VI).

The MIC Test (Appendix I) is proposed for testing of active ingredients and finished products only. The test serves to delineate the spectrum of activity of an ingredient or formula, and may be useful for determining active ingredient formulation levels, and active ingredient/vehicle interactions. MIC testing of active ingredients is performed on the organisms listed in Table A. For ingredients to be used in bodywash products it is not expected, nor required, that they demonstrate activity against all listed organisms. The MIC testing of bodywash products is done against those organisms which are most significant to this category as shown in Table VI. Time-Kill tests (Appendix II) are performed by testing the product against the significant organisms of this category (Table VI). Test concentrations are based on the actual usage characteristics of these washes.

In vivo testing may be done either by Cup Scrub methodology, or by modified Cade Handwash test. The Cup Scrub technique (Appendix III) is used to demonstrate either immediate reduction of resident skin organisms, or to show both immediate and residual activity. When used to demonstrate residual effects, testing occurs at a period of time

References

See Reference List in Tab 2 of the Background Package.