

A conversation with Philip Klepak,

Director of Technical Services for the antiperspirant business of Summit Research Labs, Inc

EURO COSMETICS: *As a Global Leader in the field of Antiperspirant Actives and over 100 years of combined experience you are at the leading edge of antiperspirant innovation. What is the key of your success?*

Philip Klepak: We have significant R&D expertise and capabilities derived from years of experimentation and development that has resulted in us leading the industry in innovations. This includes chemical modification and synthesis of both Al and Al/Zr actives, process scale-up, analytical characterization of the various polymer distributions, sweat reduction efficacy assessments, market analyses, prototype development, seminars, etc. We work very closely with established and new customers by establishing actual relationships to assist them in their development efforts.

EURO COSMETICS: *You represent the combination of Summit Research Labs, Rebeis, and the BK Guilini Cosmetics business unit of ICL Performance Products. What are the possibilities?*

Philip Klepak: We now have four world-class, state-of-the-art manufacturing facilities located in the USA, Germany, and China. We actually have two facilities in the USA. These plants are all FDA-registered to produce OTC drug actives that are monographed in the USP. These locations give us a true global footprint that allow us to efficiently supply our liquid and powder actives globally. Technical Service, which plays a key role in assisting our customers to use our actives, and to solve the various problems they encounter, are located in the U.S. and Germany, which again makes us quite effective in establishing contact with customers. Finally, these multiple locations allow us to minimize risk to our customers from unexpected occurrences.

EURO COSMETICS: *What actives do you offer to support your customers?*

Philip Klepak: Our customers represent



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every significant manufacturer of antiperspirant products be they multi-national, regional, or local marketers. We have the predominant global market share. Summit Research Labs offers commercially a full range of aluminum-only and aluminum zirconium actives, in both standard efficacy and enhanced efficacy types. We also produce customer specific actives in which the aluminum and zirconium polymer distributions are optimized for targeted sweat reduction performance, fragrance friendliness, and stability. We also offer guideline formulas for every product form, and consulting advice on how to conduct hot-room clinical studies.

EURO COSMETICS: *Where can antiperspirants be used?*

Philip Klepak: First, let's briefly understand why we perspire. There are several factors which cause us to sweat. Increased body temperature due to physical activity and/or

a high ambient temperature can cause your whole body to sweat. This kind of sweating occurs to regulate the body temperature by evaporative heat loss. This sweat is released by the eccrine sweat glands, and consists mainly of water and salts.

You can also sweat due to emotional or psychological stress. This sweat is mainly produced in your armpit or on the soles, palms, and forehead. This type of sweat is not only produced by the eccrine glands, but also by apocrine glands, and consists of proteins and lipids which serve as nutrients for bacteria on the skin. The bacterial decomposition of these components is what creates the unacceptable odor more commonly known as BO.

Antiperspirants function directly on the eccrine sweat glands to reduce the flow of perspiration, and because they also exert antibacterial effects, they kill the skin bacteria and provide the added benefit of deodorancy action.

In the U.S., antiperspirants are regulated as OTC drugs, and their use is restricted to underarm application only. However, in most other geographic areas, they are regulated as cosmetics, and can be applied to other body areas such as the feet and hands. In fact, a foot antiperspirant is rational therapy because our feet are sweating all the time due to both heat and exercise, and bacteria are also naturally present on the skin. Also, as the stratum corneum is thicker on the soles, a lower molecular weight active, such as aluminum sesquichlorohydrate, is recommended over aluminum chlorohydrate. A common complication of sweaty feet is athlete's foot because fungus thrives in moist conditions.

EURO COSMETICS: *And what about the safety of antiperspirants?*

Philip Klepak: Let me state unequivocally that antiperspirants are completely safe to use despite some claims over the years to



the contrary. Let's take breast cancer as an example. For some time, various claims and rumors have circulated that suggest that the use of underarm antiperspirants cause breast cancer. The most prominent claims are that (a) cancer-causing substances are absorbed through the razor nicks from underarm shaving, and are deposited in the lymph nodes under the arm and cause changes in estrogen receptors, (b) most breast cancers develop in the upper outer quadrant of the breast because that area is closest to the lymph nodes exposed to antiperspirants, and (c) men have a lower risk of breast cancer because they do not shave their underarms.

If you study the valid published scientific literature and the websites of reputable and unbiased organizations such as the American Cancer Society, the National Cancer Institute, and the FDA, their current conclusions are that (a) there are no strong epidemiologic studies in the medical literature that link breast cancer risk and antiperspirant use, (b) it is unlikely that razor nicks are a major source of carcinogens that reach the breast cells, (c) it is not currently known if any aluminum is

absorbed through the skin.

The overall conclusion of these organizations at this point is that no clear link has been made between the use of antiperspirants containing aluminum and breast cancer.

EURO COSMETICS: *How is an antiperspirant tested for effectiveness?*

Philip Klepak: The U.S. is the only country that has quantitative standards to determine if a product can be labeled as an antiperspirant. If the product exceeds 20% sweat reduction in a minimum of 50% of the tested subjects, it can be labeled as an "antiperspirant". If the product exceeds 30% sweat reduction, it can be labeled as "extra effective". The reason to have a quantifiable standard is because it is important to assure that the perspiration reduction that is achieved is readily perceived by the majority of users.

The recommended FDA guidelines for efficacy testing involves collecting underarm sweat from panelists in a controlled environment hot room after a specified number of product treatments, and comparing the weight of sweat to baseline values prior to

the start of treatment. These guidelines are quite specific for the test subjects, the testing conditions, the test procedures, and the statistical treatment of the data obtained. As one example, test subjects must be sufficiently representative so that the differences between the highest and lowest rates of sweating among the test subjects must exceed 600 mgs of sweat in 20 minutes per underarm.

Other countries don't really have the rigorous standards required in the U.S. to label a product an antiperspirant. In the EU, there is no officially approved protocol, and for this reason, some marketed products do not qualify as an antiperspirant in the U.S. Typically, a "lighter" type of test is practiced. Summit Reheis conducts several FDA type clinical studies every year to evaluate new chemical modifications of our antiperspirant actives. We are quite knowledgeable in this area, and provide significant guidance to assist our customers.

EURO COSMETICS: *What is the difference between a deodorant and an antiperspirant?*

Philip Klepak: The terms are often confused by both consumers and the trade journals. There are functionality and regulatory differences between the products.

Deodorants are designed to reduce the amount of body odor, or mask the body odor, mainly by the use of antibacterial agents applied to the skin surface. Bacteria residing in the underarms break down sweat gland secretions such as lipids and proteins into short chain odorous molecules commonly known as body odor (BO). These products are considered as cosmetics globally. They do not help reduce sweating.

Antiperspirants are personal hygiene products designed to control both sweating and body odor. They contain inorganic aluminum and aluminum-zirconium salts that hydrolyze in sweat and form temporary gel plugs at the most upper part of the sweat glands, and thus, less sweat is secreted. Because they are exerting a physiological effect on a bodily function, they are regulated as OTC drugs in the USA, but are considered cosmetics in most other global areas. Antiperspirants actives are also antibacterial, so if a product is an effective antiperspirant it is also an effective deodorant.

EURO COSMETICS: *Are there different levels of performance possible with antiperspirants?*

Philip Klepak: There are two basic chemical classifications of antiperspirant actives, aluminum chlorohydrates (ACH) and aluminum-zirconium-glycine (AZG) complexes, and these two classes can be further divided into standard and enhanced efficacy grades. Enhanced efficacy actives contain a larger percentage of smaller aluminum polymer species. In addition, Summit Reheis has pioneered the development of the UltraZAG line of actives, which are AZG complexes that contain optimized zirconium polymer distributions.

There are two FDA effectiveness criteria. All of the approved actives will meet the FDA's basic criterion of 20% minimum sweat reduction depending on the concentration used, and the finished products can then be labeled as "antiperspirants". If the

clinically determined sweat reductions achieve 30% or higher, the finished products can further be labeled "extra effective".

In addition to these two official regulatory standards, the industry has created an unofficial third category referred to as "clinical strength". These products contain the highest level of UltraZAG actives allowed in the Antiperspirant monograph, and they are typically positioned for people with problem perspiration, or hyperhidrosis, or those who want a product that doesn't require a prescription.

EURO COSMETICS: *Can antiperspirants cause fabric stains?*

Philip Klepak: Fabric staining is a very complex phenomenon that is influenced by many factors such as the type of active, the formulation, the fabric type, trace multivalent ions in the wash water, skin lipids, the laundering procedure, etc. I will keep my explanation relatively simple as there are still many theories on the cause of fabric staining.

Sweat itself is clear and colorless. The active and some other formula ingredients (clay, fragrances) can react with the components of eccrine sweat and skin sebum to cause a fabric yellowing reaction over time due to repeated and prolonged exposure. This is especially true for cotton fabric. The stain once set is difficult to remove with normal washing.

White stains on clothes, more commonly referred to as white marks or residue, are typically product transfer from the formulation to the clothing. To combat this, make sure your antiperspirant is completely dry before dressing, or use a product that is specifically formulated to leave no white marks on your clothes. Also, use a controlled amount of applied product to minimize build up in the fabric.

EURO COSMETICS: *What are some of the more important market and product trends in the antiperspirant category?*

Philip Klepak: Underarm products are expected to reflect a significant increase in demand over the next several years. There are four trends that I would like to men-

tion; performance, aerosols, skin benefits and the rising middle class.

The marketed brands are starting to address very high performance products, and consumer interest is high. While 24 hour protection is still the most common efficacy claim, it is becoming more common for products to claim 48 hours protection, clinical strength action, effectiveness for hyperhidrosis and stress sweating, maximum protection, and thermal heat protection claims to guard against extremely high temperatures. When required, Summit Reheis will adjust the chemistry of their actives to deliver this higher performance. In my opinion, the most important feature for the consumer is efficacy.

Aerosol products are gaining global momentum with increasing launches in all regions. They are even making a comeback in the U.S. Aerosol formulations in the broad personal care category are surging with antiperspirant-deodorants being the largest single sub-category. Two noteworthy trends are the introductions of compressed aerosols with environmentally friendly and sustainable packaging claims, and very dry powder sprays that instantly dry and leave no visible white residue. Aerosol filling figures show year to year growth with the top three regions being Latin America, Asia Pacific, and the Middle East/Africa.

The industry and consumers are driving the inclusion of more skin benefits such as moisturization, antibacterial action, repair of minor damage to the underarm skin, nourishment of underarm skin, retarding the regrowth of underarm hair, and skin lightening/brightening features in Asia.

The growing middle class population, rising income, and improvements in standards of living in developing countries are fueling the growth of antiperspirants from occasional use to discretionary use products. Demand is especially increasing among young people and females where usage in daily grooming routines is becoming more common.

EURO COSMETICS: *Thank you for the conversation.* ■