Abstracts

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Global Regulations of Sunscreens

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On June 1, 2006, the trade associations representing the personal care industry of the European Union, the United States, Japan and South Africa agreed on an International Sunscreen Protection Method. What will this mean? Sunscreens are regulated throughout the world either as cosmetics, over-the-counter (OTC) drugs which do not require a governmental pre-approval or OTC drugs that require a pre-approval before they are placed on the market. Regardless of how they are regulated, all of these product regulations are very similar concerning sunscreens! Each country has a pre-approved list of permitted UV filters, an accepted method of running efficacy by SPF determination, and regulated labels. Some countries have approved methods for UVA claims and water-resistance testing. The latest changes are in Australia, where some sunscreens will be regulated as cosmetics based on SPF and claims, and Canada, where some sunscreens will be regulated as Natural Health Products depending on their actives! And now here comes a new variable, the harmonized SPF method. What confusion! This paper will cover the different SPF test methods (Harmonized, Australia, and US-FDA) along with the formulations of reference standards, currently approved UVA methods, water-resistant testing, some labeling requirements and finally a brief review of cGMPs and other requirements for the US. It will have an update of the recent changes in regulations and cover the approved UV filters permitted in the US, EU, Japan, Canada and Australia as well as their maximum use level and correct ingredient designation. There is also a master cross reference list by INCI designation.

Scientific Characterization of Subclinical Skin Changes by Noninvasive Biophysical Methods for Development of More Efficacious Skincare Products

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In 1966, after finishing only my first year of a residency program, I went to the United States to study for 2.5 years with Dr. Albert M. Kligman the analysis of functional properties of various skin changes in vivo using aged skin, various types of dermatitis and topically applied steroidinduced atrophy as experimental models. Ten years later, I luckily found that measurements of high frequency conductance and capacitance of the skin enable us to evaluate the skin surface hydration state that determines the softness and smoothness of the skin and in particular to detect even subtle skin changes induced by changes in our environmental or by the application of skincare products and cosmetics. Employing such noninvasive biophysical instruments, I have analyzed the functional properties of normal and abnormal skin changes including subclinical skin changes such as atopic xerosis, senile xerosis, scars and effects of various topical and systemic agents. From these studies it became apparent that as long as a certain level of barrier function was retained skin surface hydration is a more important factor for enjoying a good quality of life. We also succeeded in confirming the effect of corneotherapy, the term so pertinently suggested by Dr. Kligman for the beneficial effects of skincare products. We could show that their daily application definitely improves the condition of subclinical skin problems. Further progress in such instrumental analysis of skin properties will greatly aid us in the future in selecting a more desirable skincare product on an individual basis.

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Differential Toxicity on Monocytes and Monocyte-Derived Dendritic Cells: A New Tool to Differentiate Allergens from Irritants?

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Phenotypic activation of monocyte-derived dendritic cells has been proposed as an in vitro alternative assay to discriminate potential sensitizers from irritants, but the sensitivity of the assay remains controversial. In this study, we first determined the dynamic range of expression of activation/maturation markers on human monocyte-derived dendritic cells cultured in the presence or absence of transforming growth factor B (TGFB). On day three of culture, most monocytes had already differentiated into dendritic cells that expressed low levels of costimulatory molecules especially in the presence TGFB Treatment of 3-day-old TGFB-treated monocyte-derived dendritic cells with several chemicals at sub-toxic concentrations induced significant phenotypic changes for all the strong and mild sensitizers tested, whereas the irritant sodium lauryl sulfate had no effect. However, a very large variability was observed among the experiments. Most interestingly, we could show here for the first time that at concentrations sub-toxic for monocyte-derived dendritic cells all the allergens tested induced monocyte apoptosis within two days of culture. In contrast, sodium lauryl sulfate displayed similar toxicity on monocytes and monocytederived dendritic cells and these results were confirmed with other irritants such as benzoic acid or methylsalicylate. Although testing of far more chemicals is required, these results indicate that differential toxicity of chemicals to monocytes and monocyte-derived dendritic cells could be a rapid, simple and valuable tool to differentiate sensitizers from irritants.

Use of Associating Polymers as Multifunctional Thickeners: Studies of Their Structure in Aqueous Solutions via NMR, QELS, Fluorescence, and Rheology Measurements

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The solution properties of an associating polymer were studied by NMR, quasi-elastic light scattering (QELS), fluorescence, and rheology measurements. An associative thickening (AT) polymer was designed having a nonionic poly(ethylene oxide) backbone with long alkyl chains at both ends to achieve high viscosity even at relatively high salt concentrations and over a wide pH range. This study focuses on the associative state of the polymer in aqueous solutions at various polymer concentrations. In a fluorescence probe study using pyrene a spectral change in the I_3/I_1 ratio was observed for pyrene at a polymer concentration (C_p) of 3×10^{49} , indicating an apparent critical concentration (cmc) of the

amphiphilic polymer. The viscosity, self-diffusion coefficient (D_{sel}), and hydrodynamic size (R_h) distribution measurements at various Cp all suggest that there is a second transition at Cp ≈ 0.4%. Although we observed the discontinuity in viscosity, D_{mb} , and R_h at $C_p \approx 0.4\%$, no changes in the relaxation times (T₁ and T₂) were recognized for either the alkyl chain or the ethylene oxide moiety of the polymer at $C_p = 0.1 - 1\%$. These data suggest that there are no structural changes or phase transitions at $C_p \approx 0.4\%$, but that intermicellar networks are presumably formed by bridging of the end alkyl groups of the polymer, which is driven by hydrophobic forces. Because the polymer forms networks by hydrophobic interaction and the polymer itself is nonionic, the viscosity of the polymer solution was influenced very little by either the addition of salt or a pH change, as would be expected. The dynamic viscoelastic study revealed that the polymer solution exhibits a single mode Maxwell type relaxation behavior with a terminal relaxation time of about 0.61 s, which imparts a unique flow appearance to the polymer solutions. The time course measurements of the dynamic elastic modulus of the stratum corneum revealed that the polymer has excellent potential for skin softening. It was concluded that the associative thickening polymer not only is a useful thickener with a salt and pH tolerance but also has beneficial skincare effects.

Blackberry Leaf Extract: A Multifunctional Anti-Agin;

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Matrix metalloproteinases (MMPs) play a major role in wrinkle formation. Their expression increases with aging an is further enhanced by UV irradiation. Blackberrry (Rubu fruticosus) leaf extract has been shown to suppress MMP-1, 2 and -9 in cell-free assays. We have now further explored the activity of this extract. The effect on MMP-1 expression at the protein and the mRNA level was investigated using non irradiated and UVA-irradiated human dermal fibroblasts. The extract showed a dose-dependent reduction of the MMPprotein level of both irradiated and non-irradiated cells wit an almost complete inhibition at a dosage of 0.1%. MMPmRNA expression of UVA-irradiated cells was decrease after preincubation as well as after postincubation with the extract. Best results were obtained with combined pre- and posttreatment (0.1% extract led to 59% reduction in comparison with the respective control). Moreover, we found that blackberry leaf extract inhibits IL-10, a cytokine know to induce MMP expression. At a dosage of 0.2% the inhibition was 40% compared with that of the stimulates control. The extract also exhibited a potent radical scavengin activity comparable to that of a-tocopherol as was shown by the ABTS assay. Taken together, these biological activitie make blackberry leaf extract a highly efficien multifunctional anti-aging active.