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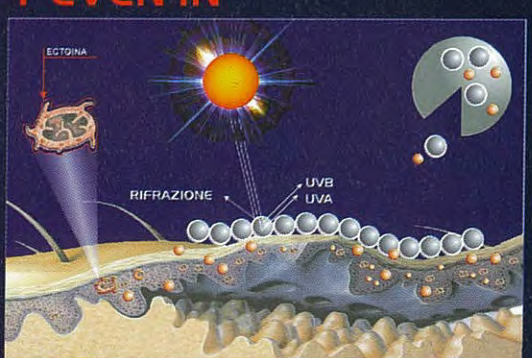

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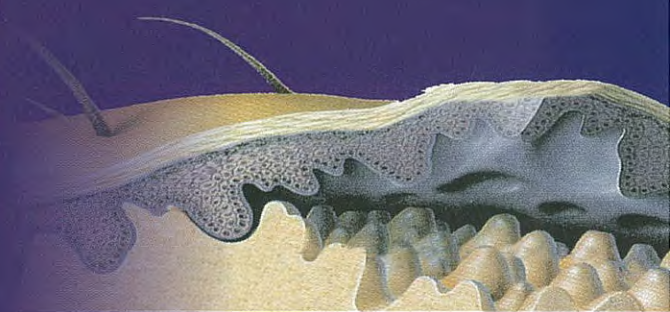

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Quarterly Review of Cosmetic Dermatology

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I'm confident our Society would greatly benefit from their knowledge and experience.
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I.S.C.D. Secretary General
Pierfrancesco Morganti Ph.D.

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Trimestrale di Dermatologia Cosmetologica
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J. Appl. Cosmetol. **24**, 47-54 (April/June 2006)

Potassium Undecylenoyl Hydrolyzed Wheat Protein: A New Surfactant With Dandruff Control Properties

Catia Bigotti, Fabrizio Guala, Giancarlo Gazzaniga*, Elisabetta Merlo, Giovanni Villa
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Received: *March, 2006.*

Key words: *Potassium Undecylenoyl Hydrolyzed Wheat Protein; Dandruff control properties; Skin and hair disorders; Dermal innocuity; In vitro sensitization potential;*

Summary

Undecylenic derivatives are well known in cosmetics and widely used; undecylenic soaps, amides and betaines have been already on the market for many years in antidandruff and mycotic growth control field.
Potassium Undecylenoyl Hydrolyzed Wheat Protein is obtained grafting undecylenic acid to hydrolyzed wheat protein. This surfactant maintains the properties of the molecules from which derives and can find several applications in personal care.
The work will illustrate the properties of Potassium Undecylenoyl Hydrolyzed Wheat Protein in dandruff control field.
The results of an *in vivo* test made using Piroctone Olamine as a control will be shown. Mycotic growth control capacity will be also described. Dermatological innocuity will be shown through different *in vivo* and *in vitro* tests.
Furthermore the sensitization power of this surfactant compared with classical antidandruff agents will be described using Interleukine-1α secretion as a parameter to be evaluated.

Riassunto

I derivati undecilenici sono ben noti in cosmetica e largamente utilizzati; saponi, amidi e betaine derivati dall' acido undecilenico sono presenti sul mercato da molti anni come prodotti utilizzati nel controllo della forfora e delle infezioni fungine.
Potassium Undecylenoyl Hydrolyzed Wheat Protein viene ottenuto unendo l'acido undecilenico con proteina idrolizzata da grano. Questo tensioattivo mantiene le proprietà da cui deriva e trova diverse applicazioni nel personal care.
Il lavoro illustrerà le proprietà di Potassium Undecylenoyl Hydrolyzed Wheat Protein nel controllo della forfora.

Verranno mostrati i risultati di un test *in vivo* fatto usando Piroctone Olamine come riferimento. Sarà inoltre descritta la capacità del tensioattivo oggetto del lavoro di controllare la crescita fungina.
L'innocuità dermatologica sarà valutata tramite diversi test *in vivo* ed *in vitro*.
Verrà inoltre descritto il potere sensibilizzante di questa molecola rispetto ai classici agenti antiforfora utilizzando la secrezione di Interleuchina-1α come parametro.

INTRODUCTION

The antifungal properties of short chain fatty acids were first recognized by the food industry, when it was noticed they inhibited fungal growth in baked goods. Soon it was found they also inhibited the proliferation of mold on cheese. Peck and Rosenfeld, in 1939 (1), observed that organic fatty acids present in sweat had fungicidal activity with no skin irritating effects, in contrast to existing preparations used for treating dermatophytoses.

These observations led to clinical trials including shorter chain fatty acids and undecylenic acid. Various formulations with undecylenic acid and its sodium, zinc or calcium salts were tried.

New studies have been made from then. All demonstrated the effectiveness of zinc undecylenate/undecylenic acid in treating tinea problems (2, 3, 4). Undecylenic acid and its derivatives are also well known for their dandruff and seborrhea control capacity. This make them useful in every skin and hair disequilibrium.

As during the keratinization process a large quantity of enzymes coming from the Odland bodies (5) is exocitated in the extracellular environment, Potassium Undecylenoyl Hydrolyzed Wheat Protein present on the skin can be split into its two components, that means undecylenic acid and hydrolyzed protein.

Free fatty acids are essential for the barrier effect of the skin (they keep skin supple, pliable and well moisturized) (5).

Hydrolyzed Proteins are able to form a continuous protective layer on skin and hair surface without influencing the cleansing or foaming capacity of formulations. This substantivity prevent penetration of other surfactants into horny layer, avoiding so dryness and irritation. They give a soft and silky feel and contribute to the ability of the skin to absorb moisture.

To hair, proteins and derivatives have anti-static effect (due probably to charge neutralization and moisture retention), are substantive, film forming, moisturizing and texturizing. They can also reduce damage resulting from permanent waving, oxidative dyeing, bleaching processes and UV radiations.

Potassium Undecylenoyl Hydrolyzed Wheat Protein can be therefore regarded as a mild surfactant able to supply skin and hair with their physiological components (proteins and fatty acids), biodegradable and effective.

Potassium Undecylenoyl Hydrolyzed Wheat Protein has the molecular structure reported in figure 1.

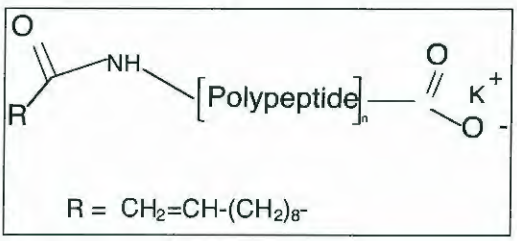

Fig. 1

It can be synthesized from castor oil by pyrolysis or by pyrolysys of methyl ricinoleate obtained by methanolysis of the oil. Castor oil is obtained from the plant of Ricinus Communis.

Undecylenic acid is also a physiological component of human skin and hair.

In Potassium Undecylenoyl Hydrolyzed Wheat Protein, the presence of the undecylenic group and the peptide residue do not impart only cleansing characteristics and skin compatibility but also functional properties.

MATERIALS AND METHOD

Potassium Undecylenoyl Hydrolyzed Wheat Protein solution was provided by Zschimmer & Schwarz Italiana, Tricerro.

Other surfactants, Piroctone Olamine and Zinc

Pyrithione solutions were provided by the same company. Reagents were analytical grade from Sigma Aldrich.
MIC tests were previously carried out by Biolab and Microna using standard protocols.
Dandruff control and in vivo innocuity tests were performed by ISPE Laboratoires while *in vitro* test by ABICH, always using standard international protocols.

Dandruff control capability

Dandruff, the most common and annoying scalp disease, induced by a disequilibrium of cutaneous homeostasis, is worsened by growth of saprophyte microorganisms.
Pytyrosporum ovale is common believed to be involved in this phenomenon; although it is observed also when dandruff is not present, it has a double concentration than in non-affected scalp (6) in the skin areas with dandruff. Furthermore, Pytyrosporum ovale is able to cleave sebum and give rise to free fatty acids. The lipoperoxides they originate are frequently responsible for irritation that can make worse dandruff phenomenon (6).
MIC (Minimal Inhibitory Concentration) of Potassium Undecylenoyl Hydrolyzed Wheat Protein towards Pytyrosporum Ovale and Malassezia Furfur was determined in a serial dilution test in liquid broth at pH 5.5. Table I shows the obtained results (7).

Tab. I

Microorganisms	MIC in %
Pytyrosporum ovale	2.5
Malassezia Furfur	3.5

An in vivo test was also performed comparing different samples. Piroctone Olamine, a well-known antidandruff agent, was used as a reference. Sample examined were the following:
Sample A = Sodium Laureth Sulfate (10.5% active matter) plus Potassium Undecylenoyl Hydrolyzed Wheat Protein (4% as it is)
Sample B = Sodium Laureth Sulfate (11.25% active matter) plus 0.75% Piroctone Olamine.
Sample C = Sodium Laureth Sulfate (10.9% active matter) plus Potassium Undecylenoyl Hydrolyzed Wheat Protein (2.5% as it is) plus 0.15% Piroctone Olamine.
30 volunteers aged between 18 and 60 years with dandruff problem had to use one of the three samples at home at least three times a week for about one month. Dandruff scales were weighed before and after the treatment. Means values and standard deviations were calculated. Figure 2 shows the obtained results (8).

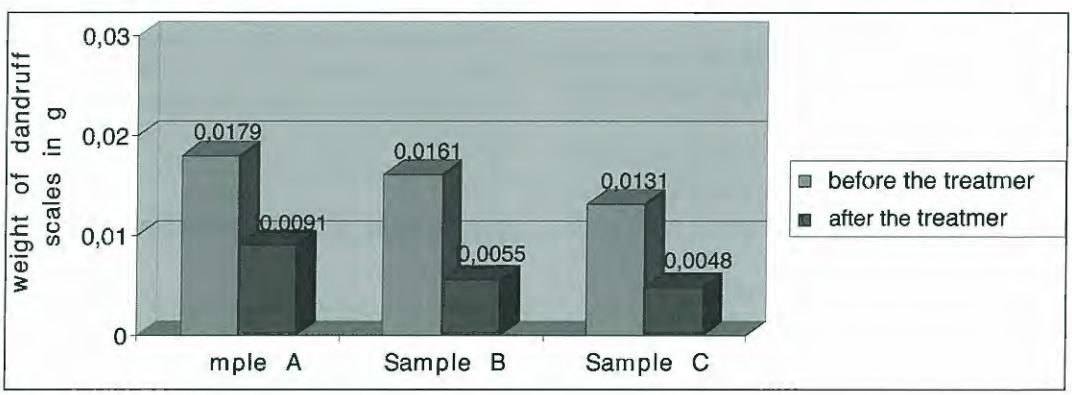

Fig. 2

The effectiveness of the three samples was statistically compared and all they showed an effective reduction of dandruff scales weight ($p < 0.1$).
The three samples were then statistically compared by mean of Analysis of Variance and no differences in their activities were found ($p > 0.1$).

Skin and hair disorders

Many microorganisms are involved in skin and hair disorders.
Pityrosporum ovale is believed to be involved in many skin disorders, such as seborrhoic dermatitis, folliculitis, confluent and reticulate papillomatosis and psoriatic lesions (9).
Tricophyton and Epidermophyton are fungi responsible for skin, hair and nail disorders. They attack keratins and cause many pathologies. We remember tinea capitis, typical of children, tinea barbae, tinea corporis, tinea pedis (the most widespread in Italy) that is typical for sportsmen and people who attend swimming pools and showers in crowded places and gives the so called athlete foot, tinea favosa (typical for Africa and Medium Oriente), tinea cruris (for inguen) and tinea unguium (10).
Candida Albicans is also a problematic microorganism.
MIC (Minimal Inhibitory Concentration) of Potassium Undecylenoyl Hydrolyzed Wheat Protein was determined in a serial dilution test in liquid broth at pH 5.5 with different microorganisms. Table II shows the obtained results (7,11).

Table II

Microorganisms	MIC in %
Pytyrosporum ovale	2.5
Malassezia Furfur	3.5
Ephidermophyton	3.5
Tricophyton Mentagrophite	3.5
Candida Albicans	1.0

Skin with mycosis or excessive bacterial development is often irritated; a mild detersion becomes important in order to prepare the skin surface to pharmaceutical treatments and to restore its natural acidity.
Potassium Undecylenoyl Hydrolyzed Wheat Protein maintains the skin compatibility characteristics of hydrolyzed proteins and can therefore help the skin to be well moisturized.

Dermal innocuity

Skin irritation was evaluated through a patch-test on 20 volunteers (12). The method consists in an occlusive application of the product by means of Finn chamber (aluminium cells of 20 microliters volume) on subjects' volar part of the forearm. The irritating activity was clinically evaluated by observing the erythema induced by the product:
- 30 minutes after application (immediate irritative power)
- 48 hours after application (irritative power)

The substance was tested at a concentration of 22% as it is.
The immediate irritative power and the irritative power were separately evaluated.
The irritative power was evaluated considering:
- the number of reactions that the product caused related to the total number of subjects
- the severity of the irritative reactions.

Potassium Undecylenoyl Hydrolyzed Wheat Protein was void of any irritation potential.
Hypoallergenicity was evaluated through a patch test on 20 volunteers (13).
The method consists in an occlusive application of the product by means of Finn chamber (aluminium cells of 20 microliters volume) on subjects' volar part of the forearm for 48 hours.
After the removal of the occlusion, the cutaneous reactions induced by the product are evaluated. These evaluations are performed 24 and 48 hours later.

The repeated control of the treated areas allows to trace the presence and/or the activity in elicitation of cutaneous reactions of common allergens.
The allergic potential is expressed as a percentage of allergic reactions and it is evaluated considering:
- the number of reactions observed
- severity, type and duration of reactions.

Potassium Undecylenoyl Hydrolyzed Wheat Protein tested at 22% as it is can be classified as not sensitizing.
In vitro methods are an interesting alternative system to traditional in vivo tests to evaluate biological properties of cosmetic ingredients and products, according to the current European cosmetic rules that ask manufacturers to assess the product safety, without employing animals.
Citotoxicity tests can be carried out in order to evaluate *in vitro* the citotoxicity of cosmetic ingredients on keratinocytes coltures. The *in vitro* test on skin-derived cells is a simplified but yet very informative model of the reactions that may occur in vivo.
The test was performed on a 3D epidermis obtained from epidermal keratinocytes seeded on a collagen matrix and grown in a serum-free medium to reach a multilayer conformation with a differentiated stratum corneum at the surface.
The products to be tested is placed in contact with the 3D epidermis for 24 hours. Sodium Lauryl Sulfate is used as a reference.
At the end of the exposure period, the epidermis layers are disrupted with the enzyme trypsine and the cytotoxicity is evaluated trough the quantification of surviving cell percentage.
Surviving cells are able to cleave a dye (MTT) in order to have a coloured solution that can be spectrophotometrically evaluated.
The absorbance is measured at 570 nm on a microplate reader, with background reading at 690 nm.

The results of the MTT test are expressed in terms of viability:

$$\% \text{ Viability} = \frac{OD_{570} \text{ treated cultures} \times 100}{OD_{570} \text{ untreated control cultures}}$$

Potassium Undecylenoyl Hydrolyzed Wheat Protein tested at 4% as it shows a percentage of cell survival higher than 100% (14).

In vitro sensitization potential

Under normal physiological conditions, resting skin keratinocytes produce usually a number of cytokines. Under stressful conditions, such as exposure to ultraviolet light, tumor promoters or chemical agents, epidermal keratinocytes release the inflammatory cytokines interleukin-1α (IL-1α), interleukin-1β (IL-1β), tumor necrosis factor-α (TNF-α) as well as interferon-α (IFN-α) and Interleukin 6 (IL-6) which trigger cutaneous inflammation. Consequently, the appearance of these cytokine markers in the cell culture medium suggests the initiation of a inflammatory cascade and therefore, IL-1a and TNF-a are excellent indicators of skin inflammation.
In this study, the sensitization potential of Potassium Undecylenoyl Hydrolyzed Wheat Protein was compared with the classical anti-dandruff agents. In the study IL-1α has been determined using ELISA test kit.
The test allows the titration of cytokines in the cell medium by reading the absorbance at defined wavelenghts, after specific identification with colorimetric reaction based on antibodies.
Sodium Lauryl Sufate (SLS) 0.5% was used as a reference.
Potassium Undecylenoyl Hydrolyzed Wheat Protein (PUHWP) was compared with solutions of 0.75% Piroctone Olamine and 1% of Zinc Pyrithione.

Tab. III

	pg/ml IL-1 alfa			
	SLS 0,5%	Potassium Undecylenoyl Hydrolyzed Wheat Protein (PUHWP) 4%	Piroctone Olamine 0,75%	Zinc Pyrithione 1%
2 h	42	24	29.5	15
6 h	52	39	44	28
18 h	789	42	76	60

Table III shows the obtained results.
Potassium Undecylenoyl Hydrolyzed Wheat shows the lowest inflammatory potential, mainly increasing time contact. It is less toxic than traditional antidandruff agents and it can be used at higher concentrations.

CONCLUSIONS

Surfactants are nowadays not only surface modifiers, dirt removers and/or foam boosters but also multifunctional molecules.
Potassium Undecylenoyl Hydrolyzed Wheat Protein offers a mild and effective solution for dandruff problem and skin/hair disorders.

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New Derivatives For Magnifying Skin Pigmentation

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Received: *May 2006. Presented at The VII ISCD World Congress "The New Frontier of Dermocosmetology: Efficacy, Stability, Safety", Rome, 4-6 November, 2004.*

Key words: *Tyrosine; Tanning agents; Skin pigmentation;*

Summary

The application of cosmetic products containing Tyrosine is based on the concept that L-Tyrosine is the primary substrate for tyrosinase, in order to induce melanogenesis. But it has been proved that pure tyrosine, per topic application, hasn't an acceptable bioavailability. Enhancing of cutaneous absorption could be reached by utilizing derivatives of Tyrosine in the perspective of magnifying tan. Aim of the present work was to obtain new functional derivatives from Tyrosine, with innovative and proved cosmetic efficacy.
In order to increase skin bioavailability *Caproyl Tyrosine* has been obtained via the condensation of tyrosine with capryc acid, a C_{10} saturated fatty acid, delivering the equivalent of about 10% pure tyrosine.

Riassunto

L'applicazione di prodotti cosmetici contenenti Tirosina è basata sul concetto che L-Tirosina è il materiale di partenza per la biosintesi della melanina ed è quindi il pigmento responsabile del colore dei capelli e della pelle.
Il substrato primario per la tirosinasi può essere limitante; infatti differenti esperienze provano che la tirosina pura, per applicazione topica, non ha una biodisponibilità accettabile.
Numerosi derivati della tirosina sono stati realizzati per aumentare l'assorbimento cutaneo della tirosina stessa e aumentare l'abbronzatura cutanea.
Scopo del presente lavoro è stato quello di ottenere un innovativo e funzionale derivato della tirosina con un' efficacia comprovata.
Nel Centro ricerche Sinerga si è ottenuto un derivato *Caproyl Tyrosine*, mediante la condensazione di Tirosina con Acido Caprico, un acido grasso C_{10} saturo, con Tirosina, il cui contenuto è pari al 10%.

INTRODUCTION

Tyrosinase, an enzyme containing copper, catalyzes the initial stages of melanogenesis. More precisely, it catalyzes the hydroxylation of tyrosine to DOPA and a further oxidation of DOPA to DOPA-quinone. The next steps, which lead to the synthesis of the different types of melanins, occur spontaneously without an enzymatic catalyst.[1]

Melanin biosynthesis depends not only the activity of tyrosinase, but also the bioavailability of tyrosine. In fact, it is well known that in a biologic synthesis, increasing the concentration of the starting substance also increases the quantity of the synthesized molecule. This is also true in the formation of melanin, where the UV rays stimulate the process of melanogenesis, reducing tyrosine in cells and at the same time leading to an insufficiency of tyrosine.[2]

The pigmentation of human skin could be the result of two different mechanisms: the melanin's biosynthesis at the level of melanocytes; and a simple reaction between skin proteins and specific reactive substances at the level of the stratum corneum.[3,4]

Almost certainly, tanning is a complex reaction. One report delineated a number of the paracrine factors made by keratinocytes that stimulate tanning normally in the skin. These include alpha-melanocyte stimulating hormone (a-MSH), adrenocorticotropin hormone (ACTH), and endothelin 1, all of which stimulate melanogenesis; factors such as basic fibroblast growth factor (bFGF), which can increase the number of melanocytes in skin; and agents such as nerve growth factor (NGF), which can preserve melanocytes in skin that might otherwise be lost.[5]

A second category of agents that have been identified are molecules involved in the intracellular signal transduction pathways that lead to tanning, such as cyclic AMP, which mediates MSH-induced tanning; protein kinase C (PKC) beta, which activates tyrosinase and enhances melanogenesis; nitric oxide, which is released by diols and stimulates tanning. DNA fragments released during the course of repair of UV-induced DNA photoproducts might also enhance tanning, according to this same report.[5]

Tyrosine and Derivatives

All these considerations led to possibility of cosmetic products containing L-tyrosine, using the concept of tanning magnifier as an agent that is able to enhance the coloring of the skin. Thus, attempts to induce melanogenesis by L-tyrosine are based on the concept that the primary substrate for tyrosinase may be the limiting factor in melanogenesis.[6,7] But different experiences have proved that pure tyrosine applied topically does not have acceptable bioavailability, and it is also an irritant ingredient. In fact it is soluble only at pH>11.4, a value at which keratin destruction occurs. At lower pH, L-tyrosine crystallizes, because it can not be absorbed. In fact it has a poor solubility in water (0.05 g/dl at RT). Other experiments validate that minimum concentration of L-tyrosine in the applied product must be more than 0.4%, the level at which one first notices an increase of melanogenesis.[2,8]

Several derivatives have been created to enhance cutaneous absorption of L-tyrosine itself. Among these are L-tyrosine copper salt, N-acetyl-L-tyrosine,[1] N-chloroacetyl-L-tyrosine, N-P-toluensulfonyl-L-tyrosine, L-tyrosine methylester hydrochloride and recently alpha-linoleoyl tyrosine.[9] As disclosed in a recent L'Oréal patent,[10] n-acyl amino acid esters (in particular isopropyl N-lauroyl sarcosinate) are considered tanning magnifiers or enhancing agents because some compositions containing them (with other cosmetic ingredients) are able to increase the level of tanning or skin browning.

The release of L-tyrosine is mediated by enzymes activated by UV rays. This fact was demonstrated by tests utilizing water-soluble derivatives marked with tritium, formulated in a cream at 1%, and applied on the skin of rats. Radiography revealed the presence of tritium in the basal layer and in the dermis.[8]

In the Sinerga R&D laboratories we sought to increase the skin bioavailability of tyrosine. First we obtained caproyl tyrosinic acid via the condensation of tyrosine with capric acid, delivering the equivalent of approximately 10% pure tyrosine.[11] The condensation product is a water-soluble lipoaminoacid, in which capric acid, a C_{10} saturated fatty acid, is able to produce a hydrophilic molecule with excellent affinity for the skin. From the condensation product we obtained two new forms:

- The lipophilic form has the INCI name Caproyl Tyrosine acid (and) Glyceryl Oleate (and) Sorbitan Isostearate.
- The hydrophilic form has the INCI name Potassium Caproyl Tyrosine (PCT) (Figure 1), an easy-to-use N-acyl derivative of tyrosine. It is a clear liquid that is completely water-soluble and compatible with traditional cosmetic ingredients, similar to other lipoaminoacids, oligopeptides and water-soluble amino acids. Its physical properties are described in Table I.

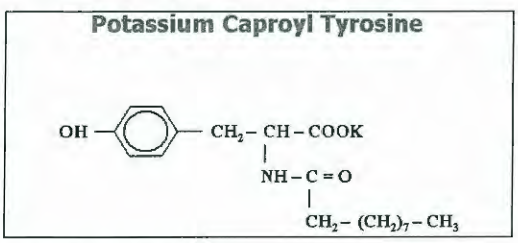

Fig. 1 Molecular formula.

Tolerability

The toxicological profile of PCT was obtained by an in vitro test with the aim of determining the ingredient's potential dermal irritation. This in vitro test, the Irritection Assay System, is a reliable substitute for the patch test normally used for this characterization.[12]

A standard concentration-dependent dose-response study was performed with the dermal Irritection test method. Results of the study indicated that the sample was classified as a non-irritating agent (score = 0.63).

Tab. I
Properties of potassium caproyl tyrosine

Aspect	clear liquid
Color	yellow
Odor	light
pH (c=10)	6.5 – 7.5
Solubility (water)	complete
Active substance (%)	28 – 32

Evaluation of the Pigmentation Efficacy After UV Irradiation

Furthermore it has been made the evaluation of the skin pigmenting properties of a cosmetic product after exposure to UV-radiation[13,14], on volunteers. The product (Potassium Caproyl Tyrosine), has been compared with a placebo and a control, untreated, area for three consecutive weeks, using a solar simulator.

MATERIALS AND METHODS

PCT was formulated at 5% concentration in a emulsion-gel, applied on the back of 12 volunteers (Fitzpatrick phototypes II, III, IV) for three consecutive weeks. UV irradiation was delivered using a solar simulator.(Multiport Solar UV Simulator Model 601, Solar Light Company, Philadelphia, Pennsylvania, USA).

The effect on the skin was evaluated with chromameter (Chromameter CR-300 Minolta, Minolta GmbH, Germany) up to 3 weeks after application.11 The parameters (L*, b* parameters, ITA° value), which are sensitive indexes of change in pigmentation intensity, are taken by

skin colorimetric measurements, before the product application and after several intervals. The Individual Typological Angle or ITA° value expresses the melanin index. It is calculated as a ratio obtained by complex calculations from L* and b* parameters. So, any change in the ratio might indicate a significant change in colorimetric values.

The assessment was performed on three selected areas on the volunteer's back. Each area was treated with a different sample (active, placebo or untreated), with a non-occlusive patch. A fourth area of the back was exposed to UVA-UVB rays in order to determine the minimum erythemal dose on unprotected skin (MEDu). Baseline colorimetric measurements were taken on Day 1 (T0) before irradiation and application. Measurements were also taken before application during the first week (T1-T3), the second week (T4-T8) and the third week (T9-T14). UVA-UVB irradiation corresponding to 50% MEDu was given after any application of the non-occlusive patch of the product sample or the placebo.

Variance analysis and Tukey test were carried out on the data to determine statistically significant differences among the set of values recorded at different times in the three areas.

RESULTS

Statistically significant differences among the set of values recorded at different times in the three areas have been evidenced (Table II):

- the area treated with the sample of PCT at 5% showed a highly significant decrease in ITA° values (T0 versus T3 p= 0.002 and T0 versus T14 p= 0.002)
- the area treated with the sample of Placebo did not show a significant decrease in ITA° values at any time
- the control area untreated did not show a significant decrease in ITA° values at any time

Tab. II
ITA° parameters

Time	PCT	Placebo	Control
T0	23.86 (7.9)	22.93 (8.8)	22.02 (7.2)
Week 1			
T1	20.14 (9.2)	21.72 (8.9)	20.55 (7.4)
T2	20.08 (9.3)	23.48 (7.7)	20.68 (6.3)
T3	18.68 (8.1)	20.27 (8.6)	21.10 (7.4)
Week 2			
T4	19.91 (8.8)	21.49 (8.6)	21.88 (7.0)
T5	22.58 (9.8)	23.28 (8.4)	21.14 (7.1)
T6	19.98 (8.8)	20.33 (8.1)	21.33 (6.3)
T7	21.18 (8.1)	20.10 (8.7)	22.06 (7.6)
T8	20.33 (7.3)	21.03 (8.6)	21.88 (7.5)
Week 3			
T9	21.10 (6.9)	20.22 (6.6)	21.54 (5.5)
T10	21.65 (7.3)	20.45 (6.8)	22.30 (5.4)
T11	21.50 (7.0)	20.24 (7.6)	22.53 (6.3)
T12	22.31 (6.3)	20.95 (7.7)	22.73 (6.3)
T13	20.29 (6.3)	19.93 (7.2)	22.16 (5.9)
T14	18.60 (6.1)	20.33 (6.9)	20.84 (7.1)

DISCUSSION

When the results are graphed (Figure 2), it is possible to understand the long-lasting effect of PCT. The process of melanogenesis is activated when UV rays are supplied. So when exogenous L- tyrosine (PCT) was supplied , endogenous L-tyrosine was activated too. Then melanogenesis occurs in two stages. The first is fast. The second is slow. But both need UV rays and copper to activate tyrosinase. So rapidly (T3) there is an increase of tanning, that is confirmed slowly (T14) too. Then a negative feed-back of the process could be generated; that means that cells don't produce L-tyrosine anymore because they realize that it is already present. That is an interpretation , not yet supported by in vitro results.
In the results, it can be noted[15] that the values recorded in the test areas treated with the two products are often lower than those recorded in the control area. That indicates a tendency toward a pigmentation increase. The difference of values is nevertheless not significant ($p<0.05$). PCT is significantly effective in increasing the skin tanning in comparison to the starting conditions, where a tan magnifying effect is requested, with significative efficacy, modulated in time. A similar level of significance could not be obtained in the comparison with the reference areas, probably because of the high standard deviation.
A similar level of statistical significance could not be obtained in the comparison with the control areas, probably because of the high standard deviation.

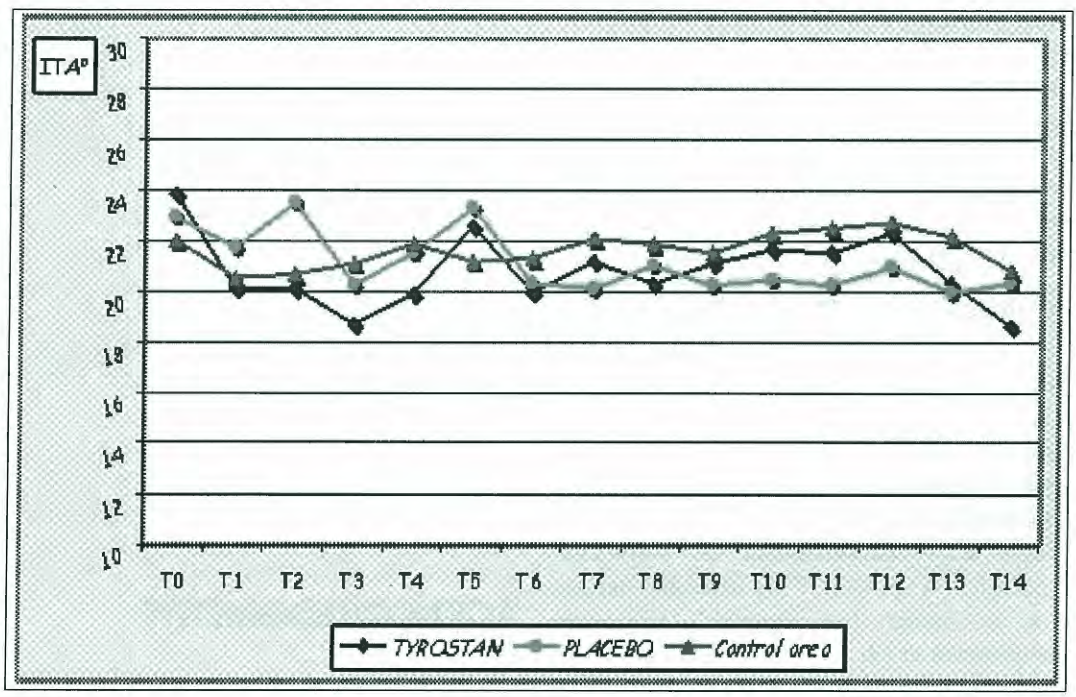

Fig. 2 Skin pigmentation results.

If baseline measurements are mathematically compared to final values it is possible to compare the tanning effects of PCT, placebo and control. The change in ITA° value from T0 to T14 is –5.3, –2.6 and –1.2 for PCT, placebo and control, respectively. Thus, application on volunteers of PCT for 3 weeks magnifies tanning or browning of the skin by about 50% in comparison to parallel application of placebo and about 77% in comparison to untreated areas.

Formulation Development

PCT is water-soluble, clear and easy to add to formulations where a tanning accelerator effect is requested, with significant efficacy, modulated in time. In formulating, the advice is to add it after the emulsifying phase at about 40°C and at any time during the cooling phase. To insure its stability, it is best to avoid its contact with strong oxidizing agents and alkaline solutions. Recommended percentage of use is 5%.
The cosmetic application as tanning magnifier has been developed in products for sun care during exposure, and for suntan maintenance after exposure and its stability over time has been confirmed in several formulations in the form of cleansers, gels and emulsions.[9]

CONCLUSIONS

Potassium caproyl tyrosine is a water-soluble, N-acyl derivative of tyrosine that increases the bioavailability of tyrosine, delivering the equivalent of approximately 10% pure tyrosine. Its effectiveness as a tanning magnifier was demonstrated with measurements of Individual Typological Angle (ITA°) on irradiated human skin. Its benign toxicological profile was demonstrated in vitro with the Irritection assay. Its use in cosmetic formulations, typically at 5%, has been demonstrated. The cosmetic application as tanning magnifier has been developed in products for suncare during exposure, and for suntan maintenance after exposure and its stability over time has been confirmed in several formulations in the form of cleansers, gels and emulsions.

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Effects of Polymer Entrapment of Prunus Spinosa Fruit Extract on its Cosmetic Efficacy

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Key words: *Prunus spinosa; Propylene glycol extract; Skin hydration; Net elasticity; Allyl methacrylate crosspolymer;*

Summary

The aim of this paper was to find out whether the entrapment of herbal extract into the polymeric 'reservoir' system affects its skin efficacy.
Propylene glycol extract of *Prunus spinosa* (blackthorn, sloe, wild plum) fruit was obtained by a triple percolation process and characterised by relative density, refractive index, pH and the content of dry matter and tannins.
The extract was incorporated into an o/w formulation, based on a non-ethoxylated emulsifier, in the concentration of 5%w/w. In addition, two modifications of the polymer delivery system based on allyl methacrylate crosspolymer were prepared, containing the extract/polymer ratio of 1:0.5 and 1:1, respectively. A short-term moisturising study of four samples (placebo cream, cream with 5% extract and two creams with 5% extract in different ratios of polymer) against a non-treated control and 10% glycerol solution was performed. A long-term moisturising study using the samples with and without polymer was then carried out, accompanied with the measurement of skin biomechanical properties. There was no evidence of significant difference in the moisturising properties of any of the three samples containing blackthorn extract in the short- term study. A two-week study revealed a pattern of slow developing, but steadily increasing effect of the sample containing the polymer entrapped extract. Similar conclusion was drawn from the cutometer results, based on the changes of the ratio parameter R5 (net elasticity).
Overall, this study has not revealed conclusive evidence that polymer entrapment of blackthorn fruit extract provides better skin performance than a non-entrapped extract. However, it is clear that the process did not hinder the moisturising potential of the herbal extract, which is an important fact when delivery system is used for the purpose other than increased skin efficacy (e.g. for stability, sebum control or odour-masking effect).

Riassunto

Lo scopo di questo lavoro è di verificare se *l'intrappolamento* di un estratto vegetale da parte di un sistema polimerico sia in grado di esaltane l'efficacia. L'estratto glicolico del frutto del *Prunus spi-*

nosa, è stato ottenuto da un triplo processo di percolazione effettuato con il glicopropilenico e caratterizzato dalla densità relativa, dall'indice di rifrazione, dal pH e dal contenuto di materia secca e tannini.
L'estratto è stato incorporato in una emulsione O/A ottenuta con un emulsionante non etossilato alla concentrazione del 5%p/p. Inoltre sono state preparate due varianti del sistema polimerico basato su un crosspolimero allil metacrilato, contenente l'estratto/polimero nei rispettivi rapporti 1:0,5 e 1:1.
Per determinare il potere idratante dell'estratto è stato condotto uno studio a breve termine su quattro campioni (crema placebo, crema con il 5% dell'estratto e due altre creme con il 5% di estratto e con diversi rapporti di concentrazione del polimero) confrontati con un controllo non trattato e con un controllo trattato con una soluzione di glicerolo al 10%.
Per determinare il potere idratante a lungo termine sono stati utilizzati campioni con e senza polimero controllandone anche le proprietà biomeccaniche nei confronti della pelle.
A breve termine tutti i risultati ottenuti per l'idratazione cutanea non sono tra di loro significativi. Con lo studio condotto per due settimane si è verificato un leggero incremento dell'idratazione con il campione che conteneva l'estratto *intrappolato* nel polimero. Analoghi risultati sono stati riscontrati nei confronti dell'elasticità. Nell'complesso lo studio non ha portato a conclusioni evidenti circa l'efficacia dell'estratto intrappolato dal polimero.
E' comunque chiaro che questo studio non esclude il potenziale effetto idratante esplicato di per sè dal *Prunus spinosa*.

INTRODUCTION

Prunus spinosa (blackthorn, sloe, wild plum) is a wild plant, used in traditional medicine and in cooking. The fruit, exceedingly astringent and reach in pectin, is usually used in jellies, syrups, conserves and as flavouring for sloe gin and other liqueurs. In addition, the pulped ripe fruit is used cosmetically in making astringent face-masks (1). In our recent study, an attempt was made to assess other potential cosmetic benefits of this plant, including its skin hydration potential (2). It was shown that the inclusion of Prunus spinosa extract in an o/w cream did have significant effect on the skin hydration state and it was related to the presence of water-binding oligosaccharides (2).

Plant extracts are known to have problematic stability profiles, due to the number and types of organic components originating from plant material. One approach to increase stability, and possibly add other benefits to the formulation, is the use of novel delivery systems. There is a wide choice of delivery systems for use in cosmetics, especially for lipophilic active ingredients (e.g. 3,4). However, the choice of delivery systems for hydrophilic actives (e.g propylene glycol extracts) is quite limited. A relatively new microparticulate delivery system based on allyl methacrylate crosspolymer is said to be suitable for both hydro- and lipophilic materials, including liquids (5). The system consists of clusters of spherical particles, with medium diameter of about 30μm, which are agglomerated together to form the porous exterior surface and a hollow interior. It is claimed to provide a 'reservoir' for the active, from which the active is released slowly, through a combination of friction and diffusion (6). This microparticulate system is potentially beneficial in improving the stability and extending the release of active ingredients, providing sebum control and increasing emulsion stability through secondary thickening (6). The aim of this study was to assess whether this delivery system was suitable for the incorporation of propylene glycol extract of Prunus spinosa and whether and to which extent the polymer entrapment affected its skin efficacy. The skin performance was evaluated by the changes in skin hydration parameters on both short and long-term bases, which in the long-term study was accompanied by the measurement of skin biomechanical properties.

MATERIALS AND METHODS

Materials

Prunus spinosa fruit extract

The fruit of blackthorn - *Prunus spinosa* (L), Rosaceae was used to make the polyol/water based extract. Propylene glycol used was 45% w/w aqueous solution. The extract was obtained at ambient temperature by a percolation method, using a plant:extract ratio of 1:2 (7). This is an exhaustive extraction method, performed in three stages, whereby only the most concentrated percolates of each stage are used and combined to obtain the final product. The resulting extract was intensely red.

Prunus spinosa (PS) extract was then characterised by relative density (1.0971), refractive index (1.3621), pH (4.09), and the contents of dry matter (6.39%) and tannins (21.85%), as reported in the previous study (2).

Test formulations

Test samples were of o/w cream type, based on a non-ionic, non-ethoxylated emulsifier - Eumulgin® VL75, INCI: lauryl glycoside (and) polyglyceryl-2 dipolyhydroxystearate (and) glycerine (Cognis, Germany). In addition, the following materials were used in the preparation of the samples: isopropyl myristate, octyldode-

canol (Eutanol®G), caprylic/capric triglycerides (Myritol®318), all supplied by Cognis, and glycerine, propylene glycol, mineral oil, potassium hydroxide and purified water (all of pharmacopoeial quality). Carbomer (Ultrez 10) was supplied by Noveon, USA, while allyl methacrylate crosspolymer (Poly-pore® E200) was obtained by Amcol, USA. All samples were persevered with 0.1% Eyxil® K 100 (5-chloro-2-methyl-3-(2H)-isothiazolone/2-methyl-3-(2H)-isothiazolone/benzylalcohol), supplied by Schulke&Mayr, Germany. The compositions of the test samples are presented in Table I.

Methods

Cream preparation method

The o/w type cream was obtained by the cold-cold emulsification method, by dispersing 20% w/w of the mixed oil phase into the aqueous phase, using 5% w/w non-ionic emulsifier and 0.6% w/w neutalised polyacrylic polymer as stabilisers. The pH values of the cream samples were within the range of 5.6-5.8.

In all samples, except placebo, Prunus spinosa fruit extract was incorporated in the concentration of 5% w/w, previously found to be effective in increasing skin hydration level (2). When polymer-entrapped extract was used, the extract was firstly mixed with allyl methacrylate crospolymer in the 1:1 and 1:0.5 ratio, respectively, until a homogeneous paste was obtained. A required amount of the paste was then incorporated into the emulsion. Prunus spinosa fruit extract was always added during the final stage of emulsion preparation, with the stirring speed not exceeding 500 rpm.

Skin hydration studies

A total of 27 healthy individuals without the history or clinical signs of dermatological disease, with normal to moderately dry skin, have participated in the two skin hydration studies. The studies were approved by the relevant ethics committee and informed consents were obtained from all volunteers.

Tab. I

Composition of test samples: placebo cream, PS (5% extract), PS 1:1 (5% extract entrapped in 5% polymer) and PS 1:0.5 (5% extract entrapped in 2.5% polymer)

Ingredients	Samples			
	placebo (% w/w)	PS (% w/w)	PS 1:1 (% w/w)	PS 1:0.5 (% w/w)
Lauryl Glycoside (and) Polyglyceryl-2 Dipolyhydroxystearate (and) Glycerine	5.0	5.0	5.0	5.0
Isopropylmyiristate	5.0	5.0	5.0	5.0
Caprylic/Capric triglyceride	5.0	5.0	5.0	5.0
Octyldodecanol	5.0	5.0	5.0	5.0
Mineral oil	5.0	5.0	5.0	5.0
Carbomer	0.6	0.6	0.6	0.6
Glycerine	5.0	5.0	5.0	5.0
KOH, 10% sol.	1.2	1.2	1.2	1.2
Blackthorn extract	---	5.0	5.0	5.0
Allyl methacrylate crosspolymer	---	---	5.0	2.5
Propylene glycol	5.0	---	---	---
Preservative	0.1	0.1	0.1	0.1
Purified water	Up to 100.0	Up to 100.0	Up to 100.0	Up to 100.0

Short-term study

Nine volunteers (7 female and 2 male, average age 28.7) were recruited for the short-term study. Corneometer CM 825 (Courage & Khazaka, Germany) was used to evaluate skin surface hydration. Corneometer measures changes in skin surface capacitance and expresses the results in relative corneometer units (rcu).The study protocol was designed on the basis of the published guidelines (8).

Three squared sites (3x3cm, 2 cm apart) on each volunteer's inner forearm were marked using a plastic template, which allowed for the testing of six sites. An experimental design including two controls (a non-treated site and 10% w/w glycerol solution) and four test samples (listed in Table I) was chosen. The room temperature was 21-22°C and the relative humidity 53% throughout the trial.

After 30 minutes of acclimatisation, the baseline values were measured, and each designated area was treated with $2\mu l/cm^2$ of a test sample (random and balanced distribution among the upper, middle and lower test sites). The test samples were applied with an Eppendorf micropipette and spread homogeneously using the flattened tip of a glass rod. On the basis of our previous results (9), a period of 45 minutes was allowed to elapse before the first measurement was taken. Three corneometer readings of each test site were recorded, with at least 5 seconds between the readings. The change in skin hydration was followed up to two and a half hours.

Long-term study

A panel of 18 volunteers (all female, average age 37.8) were recruited and provided with written instructions regarding their role in the study, after which they were asked to sign an informed consent. Volunteers were required to refrain from the use of any moisturising products on their inner forearms for two weeks before the start of the study. The left inner forearm was used as a treatment site, while the contra-lateral site served as a control. Half the panel was treated with the placebo emulsion (treatment A) and the other half with the active product, containing the extract/polymer ratio of 1:1 (treatment B).

The trial was carried out over the period of 16 days, with the volunteers applying a designated treatment twice daily for 2 weeks, followed by a two days regression period. The quantity applied was standardised to one portion obtained by a pump dispenser. Skin hydration tests were performed at baseline, 4 hours after the first application, after the 1st and 2nd week, as well as 2 days after the cessation of the treatment. Measurements were obtained 12 to 16 hours after the last product application, as suggested in the literature (10). No other products were used on each forearm for the duration of the trial.

Skin biomechanical properties

In the long-term study, skin visco-elasticity was recorded alongside skin hydration, by means of a suction-based instrument (Cutomer/SEM 575). Measurements were performed according to the manufacturer's instructions (11), using a 2mm aperture probe and the following parameter settings: 450 mbar, on-time 2 sec, off-time 2 sec, 3 repeats. This was followed by a computer-aided calculation of a series of mechanical parameters, of which net elasticity (R5) was chosen for further analysis.

Statistical analysis

The values of all observed parameters are given as means ± SD. Following a positive testing for normality, parametric tests were used in the short-term study. Data were analysed by the one-way within-subjects (repeated measurements) ANOVA, followed by Duncan multiple

range test. Differences between placebo and corresponding active treatments at distinct time points were checked by unpaired Student t-test. Due to significant differences in standard deviations, long-term study results were analysed by a non-parametric Kruskall Wallis test.

RESULTS

Results of the short-term study

Table II shows the mean corneometer readings for each treatment obtained from 54 test sites (6 sites from each of the 9 volunteers) over 150 min. Student t-test showed that the control site remained statistically unchanged during the study, while all other sites at all time points were statistically significantly higher from baseline.

Analysis of variance of each time point has shown that after 45, 90 and 150 minutes the mean readings for the four test sites and the positive control (glycerol 10%) did not statistically significantly differ from each other ($p<0.05$).

Two graphical representations of the same set of data were presented in Figures 1 and 2. Figure 1 shows the set of mean values from which their respective baseline values have been subtracted. To compensate for both initial and inter-individual differences, a further subtraction from means of their respective control values was carried out and the results presented in Figure 2. Results viewed in this manner indicate some trends, which were not apparent before. For example, after 90 and 150 min, the sample with 5% extract (without polymer) has shown the hydration potential almost identical to the one obtained by 10% glycerol. Out of the two samples with polymer-entrapped extracts, the one with the higher polymer content (PS 1:1) has shown the lowest impact on the skin capacitance, within the given time. These trends were not strong enough to be detected by the above-mentioned ANOVA analysis, most probably due to the low number of participants. It would be of interest to repeat the study with the larger number of volunteers and for a longer time period to elucidate whether these differences really exist and for how long they are detectable.

Further analysis was performed by calculating the difference to control for each treatment in each time point and presenting the results as % increase from control (Figure 4). Non-parametric analysis of this set of data has revealed significantly lower value in the case of polymer-entrapped extract containing cream after 4 hours. However, the significance ($p<0.05$) was lost after one week and was non-existent after two weeks and also after the two days regression period. The trend of consistent increase in skin hydration achieved by the polymer-entrapped extract was detectable, but not statistically significant after two days. This again may be due to the insufficient number of participants in this study.

Tab. II

Short term study: Skin hydration values in relative corneometer units (rcu) over 150 min; results are given in means ± SD; n=9

Sample	Time			
	baseline	45 min	90 min	150 min
control	37.71 ± 4.12	38.78 ± 3.21	40.17 ± 3.41	40.08 ± 4.02
placebo	40.59 ± 3.75	60.03 ± 4.05	61.49 ± 4.82	61.16 ± 3.98
PS	39.06 ± 4.24	60.04 ± 5.55	63.60 ± 3.78	63.09 ± 4.52
PS 1:1	34.89 ± 3.18	57.38 ± 5.88	58.00 ± 4.50	57.70 ± 4.90
PS 1:0.5	36.47 ± 2.98	58.28 ± 4.09	60.27 ± 5.06	58.41 ± 4.29
Glycerol 10%	35.79 ± 3.87	61.57 ± 4.75	63.04 ± 4.90	62.53 ± 5.01

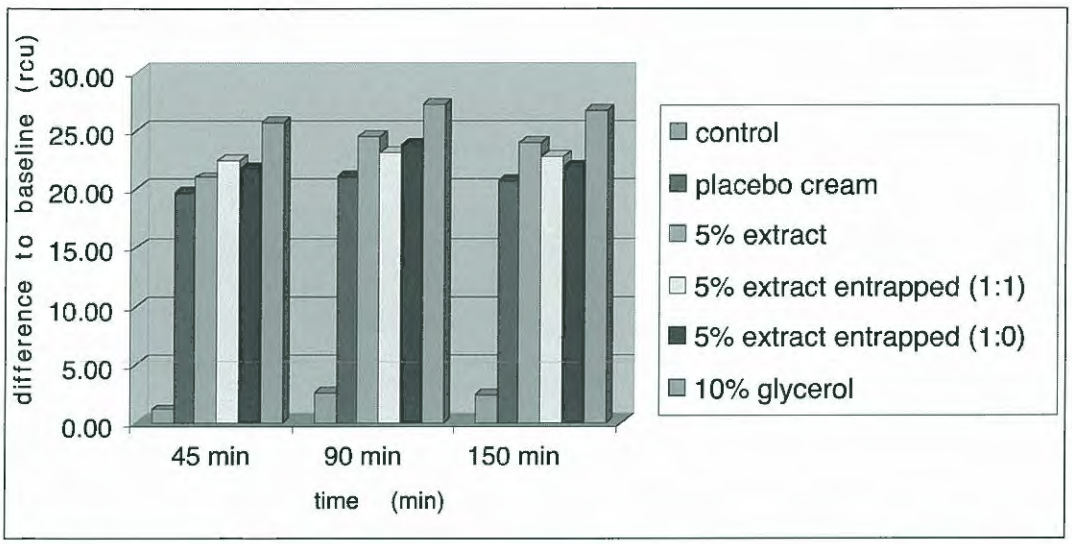

Fig. 1 Short term study: Effect of the extract-polymer ratio on skin capacitance; data expressed as difference to baseline.

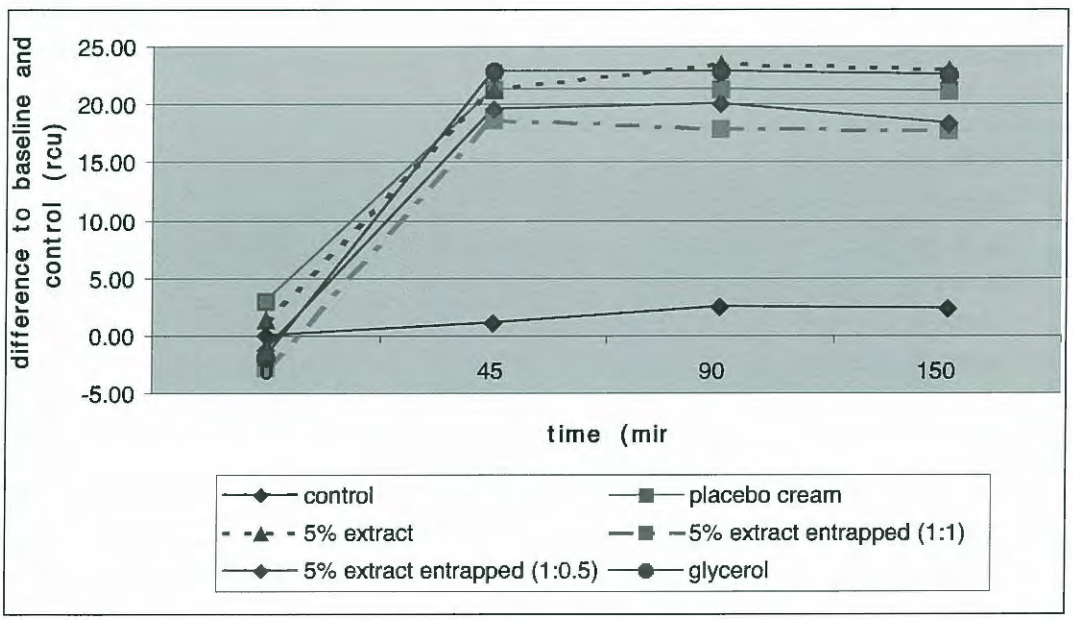

Fig. 2 Short term study: Effect of the extract-polymer ratio on skin capacitance; data expressed as difference to baseline and control.

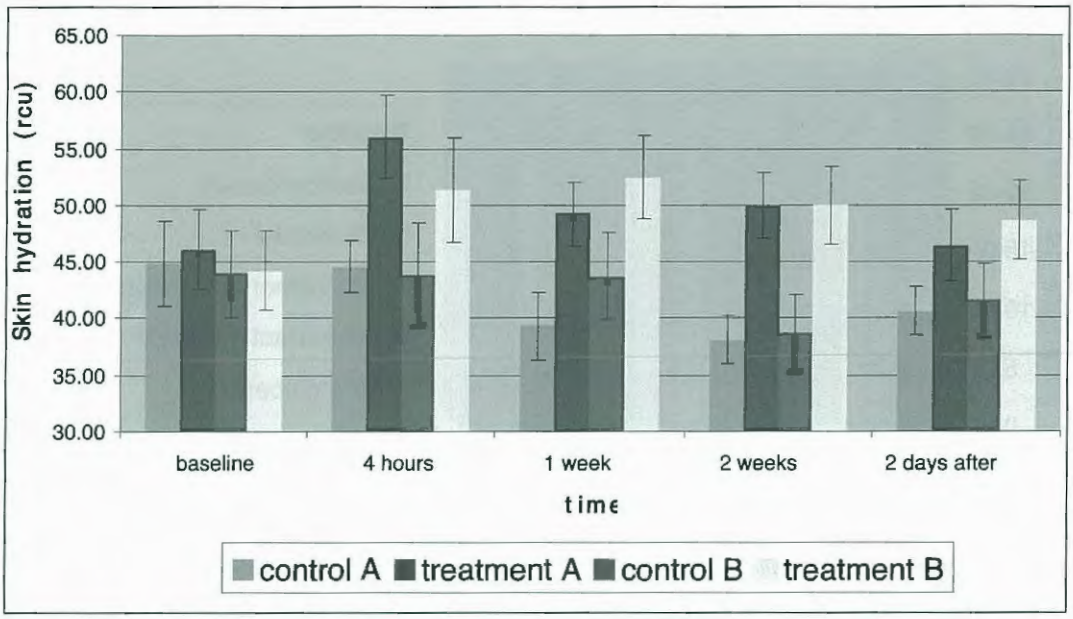

Fig. 3 Long term study: Changes in skin hydration over two weeks plus two days regression period; treatment A – 5% extract; treatment B – 5% extract entrapped in polymer 1:1; n = 9 for treatment A and B, respectively.

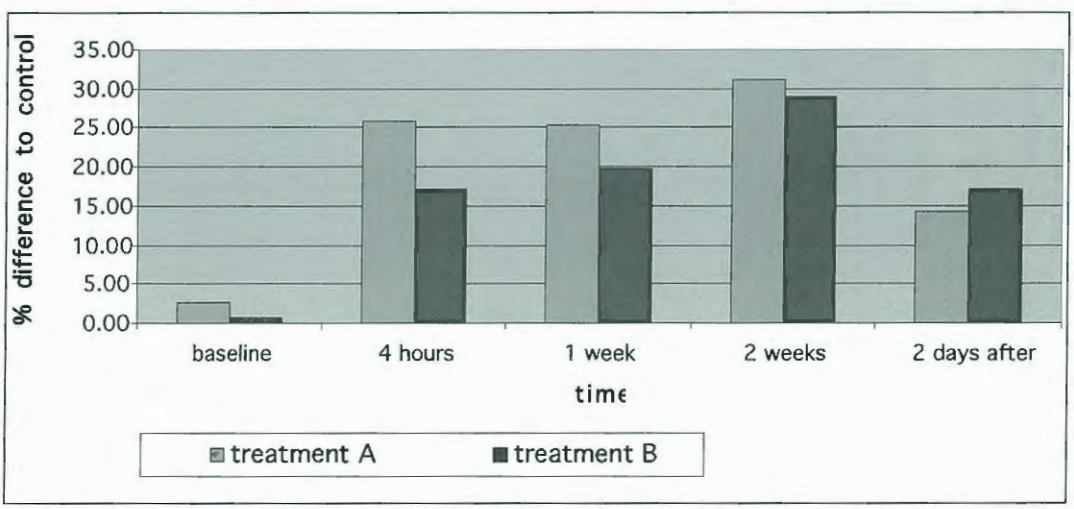

Fig. 4 Long term study: Changes in skin hydration expressed as % difference from control.

Tab. III

Long term study: Net elasticity (R5) values for group A (5% extract) and group B (5% extract entrapped in polymer, ratio 1:1); results are given in means ± SD; n=9 in each group

Time	Sample			
	Control A	Treatment A	Control B	Treatment B
Baseline	**0.8715 ±** 0.0826	**0.8741 ±** 0.0790	**0.8280 ±** 0.0720	**0.8257 ±** 0.0696
4 hours	**0.8626 ±** 0.0478	**0.8872 ±** 0.0471	**0.8399 ±** 0.0638	**0.8948 ±** 0.0699
1 week	**0.8886 ±** 0.0608	**0.9568 ±** 0.0471	**0.8465 ±** 0.0625	**0.9279 ±** 0.0762
2 weeks	**0.8640 ±** 0.0451	**0.9323 ±** 0.0537	**0.8483 ±** 0.0661	**0.9282 ±** 0.0562
2 days after	**0.8715 ±** 0.0822	**0.8741 ±** 0.0790	**0.8526 ±** 0.0700	**0.8637 ±** 0.0794

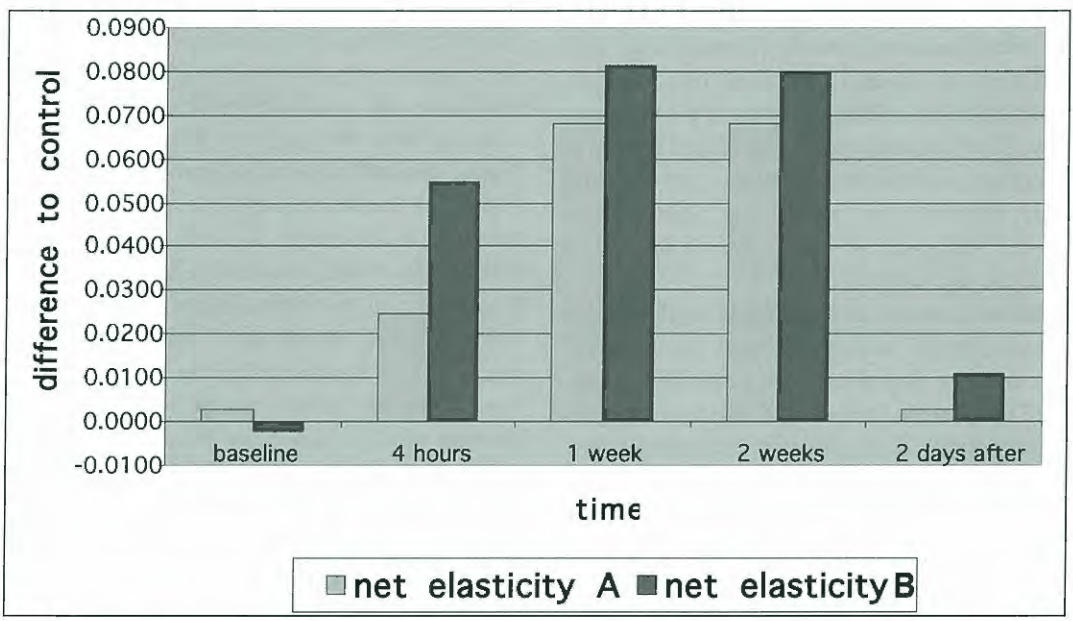

***Fig. 5** Long term study: Changes in net elasticity (R5) expressed as difference to control.*

In addition to skin hydration changes, skin mechanical properties, known to correlate with improved skin hydration, were evaluated. Out of the eight R parameters and two F (area) parameters provided by the software, the ratio parameter R5 (net elasticity) was chosen for further analysis.

When shown as difference to control (Figure 5), the net elasticity data revealed similar trend as obtained by skin hydration measurements (Figure 4), except after 4 hours, when the situation was reversed. No statistically significant difference between treatments A and B was found after 1 and 2 weeks. This was also true for the 2 days regression period, although the p value was approaching 0.05.

DISCUSSION

Modern plant extracts (as opposed to traditional ones) are normally ambient infusions, using about 50% aqueous propylene glycol at a herb/extract ratio of 1:10 (12). The extract of Prunus spinosa fruit used in this study was obtained by a pharmacopoeia-based triple percolation method (7), with the herb/extract ratio of 1:2. This resulted in a much higher concentration of the plant material in the solution, including cosmetic actives, which contributes to its considerable efficacy.

Prunus spinosa is known to be of both medicinal and nutritional interest, with different parts of the plant being evaluated in detail (e.g. 13). However, its cosmetic potential has not been explored systematically. Studies of the composition of the fruit extract have identified flavonoid glycosides, coumarin derivatives, tannins, fruit acids, vitamin C and mono- and oligosaccharides (2, 14), most of which are of interest in cosmetic formulation.

Short-term moisturiser testing is well established as a useful method for rapid determination of immediate skin effects, but with a disadvantage of insufficient time for full effects to be exerted, especially in the case of 'therapeutic moisturisers' (15). Longer-term testing overcomes this problem, while regression methods go a step further by testing residual effects of moisturisers, after the application has been withdrawn. There are many modifications of the original Kingman's regression method proposed in 1978, which lasted 4-6 weeks. They are based on the same principles, but take much shorter time, with the ultimate development of a one-week mini-regression test (15, 16). For the purpose of this study, an application period of two weeks, followed by a two-day regression period, was chosen. The first measurement was taken 4 hours after the baseline values were measured and the test product applied for the first time, in order to obtain information beyond 150 minutes available from the short-term study.

Formulations chosen for this study were based on a non-ethoxylated emulsifier of a polyglycodise type (Table I). This group of emulsifiers has been proposed as a more favourable alternative to traditionally used polyoxyethylene derivatives in stabilising o/w emulsions (17), due to their lower lipid depleting effect and smaller alterations of superficial cutaneous proteins. In our previous study, a sample based on polyglucoside type emulsifier has proven to be a superior moistureser in comparison with three other emulsion bases (18).

All four samples tested in the short-term study have shown very similar moisturising activity, which was not significantly different from each other or from 10% glycerol (Table II, Fig. 1). Higher concentration of glycerol was avoided, since it is known that the corneometer is less sensitive in the range of very high hydration values (19). Given the same content (10%) of humectants in the formulation, but combined with additional emollients (Table I), it was of interest to find out whether the cream samples would provide better moisturisation than the glycerol solution. It was not found to be the case under the experimental conditions used. Further data analysis, including deduction of the baseline and control values from the test values at each time point (Fig. 2), enabled the differences to become visible, with the sample containing the highest ratio of polymer showing consistently lower values. This finding is in line with the claim that the polymer delivery system provides slow, sustained release of actives (6).

This trend becomes more pronounced when analysing the four-hour values obtained in the long-term study (Fig. 3 and 4). The sample containing free extract (A) have exerted significantly higher skin hydration than the sample containing delivery system (B), indicating that

the entrapped extract needs some time to get released from its polymer microparticles. It is known that an active is loaded into the allyl methacrylate crosspolymer carrier through a combination of capillary action and its affinity for the polymer matrix (5). Its particle size of 30μm does not allow skin penetration, therefore the polymer and its entrapped content stay on the skin surface. It is also known that lipophilic active materials partition into the interior of the polymer network, while hydrophilic actives stay on the exterior. Both are released through a combination of friction and diffusion, and it is possible (although not tested here) that hydrophilic actives are released faster.

As the time of the study progressed to one and then two weeks, the difference between tested samples started to diminish. Two days after the withdrawal of treatment, the results indicated that the delivery system might have a longer lasting effect (Fig. 4). A new study with larger number of volunteers will have to be performed in order to test this hypothesis. However, the results of the above hydration studies have proven that the polymer entrapment of the Prunus spinosa fruit extract did not adversely affect its moisturising potential.

Assessment of skin biomechanical properties is not a straightforward task, because of the complex interactions between different skin layers. It is generally accepted that the stratum corneum contributes to the overall skin viscoelasticity, albeit less that viable epidermis and possibly dermis (20). The contribution of dermis depends on the load applied (in the case of cutometer, the negative pressure) and the diameter of the probe orifice. Therefore, the measurements of the subtle changes in stratum corneum mechanics, e.g. in response to acute hydration, are relatively insensitive. It was of interest of assess whether or not there was a correlation between skin hydration and biomechanical parameters in a 16-day regression test, and which parameter would be most suitable for this type of study.

It is well established that the deformation parameters obtained by cutometer (e.g. maximum extensibility U_f, immediate deformation U_e and immediate recovery U_r) are dependent on the skin thickness. Since the volunteers involved in the study were not an age-homogeneous group, it was clear that either a ratio or an area parameter should be used. Out of 9 ratio parameters offered by the software, the instrument manual stresses the importance of R2 (gross elasticity), a ratio between the maximum amplitude and the ability of re-deformation (11). However, the ratio parameter R5 (net elasticity) was shown to be independent of the skin thickness (21) and as such already used for comparative purposes (e.g. 22). Net elasticity is defined as U_r/U_e - a ratio between immediate recovery and immediate deformation.

In our regression study, net elasticity has shown a good correlation with the skin hydration data (Figs. 4 and 5), except for the 4-hour measurement. Short-term biomechanical effects are known to be difficult to correctly identify and it is possible that this one was an artefact due to the product residue. However, an absence of significant difference between the two test samples after both one and two weeks, as well as a higher response obtained by the delivery system after 2 days of regression, were mirrored by cutometer tests. These results confirmed the suitability of net elasticity (R5) as a biomechanical parameter to be used alongside skin hydration measurements. They also confirm that the polymer entrapment of the Prunus spinosa extract does not negatively affect the products biomechanical efficacy.

CONCLUSION

The aim of this study was not to directly assess cosmetic efficacy of the Prunus spinosa extract, since it was an object of our previous study (2),

which has shown its high moisturising potential. Considering the variety of possible cosmetic actives in the extract (including antibacterial and free radical scavenging materials), it was of interest to explore the ways of their protection when incorporated in a finished cosmetic product. A microparticulate delivery system based on allyl methacrylate crosspolymer was used and its effects on the cosmetic efficacy of the Prunus spinos a extract were assessed. It was shown that the polymer entrapment of the extract did not adversely affect its skin performance and that it was suitable as a delivery system. In addition, an indication of sustained release and longer lasting effect on both skin hydration and biomechanical properties was detected in the case of polymer entrapped extract. This hypothesis will have to be tested with larger number of volunteers in order to establish whether differences in skin performance are statistically significant.

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CHINA: A GREAT COUNTRY STILL TO BE LEARNED

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One year later, I went back to China, invited by my friend, Prof. Duo Chen, on the occasion of the Congress of the North-Eastern Dermatologists of this big populous country.
I was welcomed and received at the Shenyang airport and had the pleasure to open the congress scientific program with my presentation focused on Cosmetic Dermatology (Fig.1).

Fig. 1 Opening lecture of the Chinese North-Eastern Congress of Dermatology

The close link between dermatologists and cosmetologists is very usual in China also; in fact there the medical attendants/aestheticians work together with the dermatologists even in the hospitals (Fig.2).
The congress audience paid attention to the close connection existing between cosmetic and dietary sciences defined with one word: nutri-cosme-ceuticals.
Lutein, for instance, a carotenoid with a high antioxidant activity, recently proved to act as anti-free radicals not only at eye macula lutea level but also at skin level. Like the well-known beta-carotene, lutein is able to improve the sun protection factor (SPF) of sunscreens if added in the right dose in the appropriate food supplements.

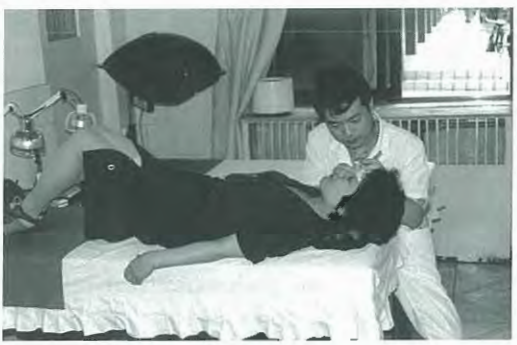

Fig. 2 Aesthetic hospital treatments in Beijing

Caffeic acid and its derivatives also, found in our Italian espresso , have an unexpected antioxidant capacity. In fact, according to recent studies, if taken at the same dosage, it antioxidant power is 7/8 times higher than the power of the well-known Chinese green tea (Fig.3).

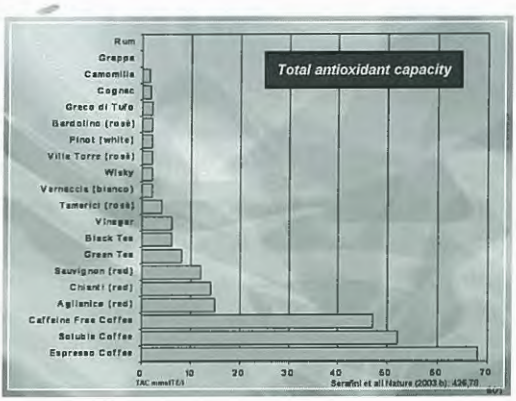

Fig. 3 The antioxidant power of some drinks

And this news fired up a great interest at the congress. Coffee extract used also topically for its lipolitic activity due to caffeine, is another example of nutri-cosme-ceutical, if taken by oral route or applied topically.

These are some of the topics I've treated in my presentation which was aimed at arouse curiosity on typical foods of the Italian cuisine, main part of the Mediterranean diet.

Since present in the Italian diet as well as in the Chinese diet with cereals, white meat and fish, fruit and vegetables were topics of the general discussion. Vitamins, microelements omega 3 and omega 6 enrich both these cuisine. In fact to take the 5 cereals as nourishing basic diet, the 5 fruits as complements, the 5 white meat as tonic and the 5 vegetables as supplements to combine their flavour in daily diet is basic part of the Chinese culture and philosophy that research even in nutrition in the Taoist harmony (Fig.4).

Fig. 4 Taoist harmony in Chinese cuisine: differentiation of food colours

In their long history, Chinese people succeeded to maintain their health and equilibrium thanks to their nutritional philosophy. Similarly, we Italians demonstrated to the whole world how the Mediterranean cuisine is undoubtedly among the healthiest.

This Congress gave me the opportunity to visit the city of Shenyang which is the capital of Manchuria, where took place the last Chinese imperial dynasty before the coming of the Republic.

Manchurians took more than fifty battles to conquer all the Chinese territory. Since the Manchurians were a minority, compared to Chinese belonging to the ethnic group Han, it was established a racial separation policy and the marriage between the two ethnic groups was prohibited.

As symbol of subjection, they forced everybody to grow hair ponytail, but at the same time thanks to their perfect organization they were able to decrease taxes, conquer numerous people such as Mongolian, Tibetans, Turkestans and Taiwanese, and to influence many states of south East Asia like Birmania and Vietnam.

At this time, an Italian Jesuit, Matteo Ricci, under the Chinese name Li Madow, entered China, lived and died in this land.

The love that Chinese have still today for Marco Polo, who arrived in1271 during Yuan dynasty, and for Matteo Ricci, who settled in 1583, link China to Italy closely.

My Chinese friend reminded me also that in 166 A.D., at the time of the emperor Marco Aurelio Antonino there were interesting contacts between the two major world empires: the Roman and the Chinese one. These contacts are well described in the Chinese text Hou Han Shu (the History of Han Posterior) dated around the V century, that treating the period 25 – 250 A.D., documents the life and the organizational structure of Rome and the roman cities since the republican period (time).

These contacts are witnessed by the prestige that silk gained in Rome. Roman knew China such the country of Seri and from that follows the Latin name of the tissue called sericum and the

sericae vestes very trendy for the roman patricians.

Probably thanks also to this secular joint between the Italian and the Chinese culture, during this journey, I had the pleasure to be appointed as Visiting Professor of the Chinese Medical University of Shenyang (Fig.5).

Fig. 5 Visiting Professor Assignment at the China Medical University

Prof. Zhao Qun, President of this prestigious medical university, invited me at the official Gala dinner. Kindness and courtesy are always been a delightful constant of the Chinese culture. Thanks to their hospitality I had the chance to visit many of their wonders and the cultural places of this magnificent imperial city; the Mausoleum Yuling demanded in 1660 by the imperator Xiaoling, the first of the Quin dynasty. In this enchanting garden, rich of magnificent historical finds, placed in special crystal reliquaries I saw all the 9 imperators till Aisin-Gioro Zaitian (1875 – 1908) (Fig.6).

In Liaoyag city, I visited the temple of Guangyou where I saw the world biggest wooden Buddha (Fig.7).

In Lianing region, in the city of Anshan, I admired the enormous Buddha chiselled in a single block of jade. On the 12 December 2002, it obtained the Guinness prize as the world biggest sculpture of jade.

Fig. 6 Manchurian dynasty Emperors

Fig. 7 The wooden Buddha in the Guagyon temple, Ashan (province of Liaoning)

A special mention is for the city of Shenyang, that deserves to be visited to enter deeply in the Chinese culture permeated of Taoist and Buddhist culture kept intact even after the dark period of the Cultural Revolution.
The harmony between nature and human beings is always at the centre of the Chinese cultural tradition and this harmonic union between the environment and man can be found even in the gardens disposition, in the flowers care, in the lakes structure, in the shape of the mountains. The delicate scenarios and the cultural variety can be seen in the whole China. And that makes this country really different.
It is to be said that the large number of the new skyscrapers built recently in Shanghai, Canton and Beijing appear amazing, and the industrial progress had in the last ten years put China at the first place in the world, at the same time the effort made to value and maintain in perfect condition the various cultural inheritances of a culture 6000 years old it is under everyone's eyes.
The most impressive thing of the modern China is the pride that each Chinese, from the richest to the poorest, has towards his culture. If we Italians are proudest than their of our origin and our culture, that from roman empire to renaissance contribute to the cultural growth of the whole European continent, we will be able to dialogue at the same level with the Chinese, exchanging all our products with this ancient people in love with the Italian culture.
With this Chinese excursus, I take the occasion to announce that on 12-14 October 2007, will be held in China an International Congress on: *NUTRI-COSME-CEUTICALS FROM EAST TO WEST: THE COMBINED REPLY FOR A GLOBAL WELLNESS,* organized in Beijing (Fig.8) under the auspices of important Chinese associations, such as the Chinese Society of Dermatology (CSD) and the Chinese Society of Medical Aesthetics and Cosmetology (CSMAC), in collaboration with the International Society of Cosmetic Dermatology (ISCD) www.iscd.it, morganti@iscd.it.
Besides the participation of renowned speakers coming from all over the world, this Congress will host booths of Italian cosmetic products, Italian raw materials and Italian food products to witness the vivacity of our SMEs.
2006 represents the year that China dedicate to Italy: let's demonstrate to our Chinese friends our industrial energy!

Fig. 8 A view of Beijing

ANTIAGING: Physiology To Formulation

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Aged skin is basically characterized by the wearing out of adipose tissue and alterations of connective tissue.

Features such as skin color, thickness, softness, smoothness, elasticity and, above all moisture content, actually change. However, senile skin atrophy is not an illness, but simply the result of an energy reduction linked to major metabolic alterations.

The connective tissue modifies its chemical-colloidal-state, shrinking in volume and completely altering enzyme reactivity particularly in the elastic fibers and collagen tissue. Several lines of evidence suggest that chronologic aging and actinic damage have distinctly different molecular mechanisms.

Signs of chronologic aging may be observed on skin that is not exposed to the snn, such as the buttock or the axilla. It is clinically characterized by fine wrinkling, atrophy of the dermis, and a reduction of the subcutaneous fat. In contrast, sun damaged skin is characterized by course wrinkling and furrowing, it appears thickened and leathery, and is slack as well, due to reduced recoil and elasticity.

Thus it is well known that aged skin particularly photo-damaged skin, is a less effective barrier than that of skin from younger individuals. Skin of the elderly cuts and does not regenerate as efficiently as that of younger individuals. For this reason products that affect wrinkles are a reality and are well established in consumer, practitioner, and corporate perspectives.

Thus the market for anti-aging products remains the largest global segment of skin care with conservative expectations to continue to grow.

Adequate sun avoidance and sunscreen use are partially prophylactic in the prevention of wrinkle formation. In addition, consumers desire a feeling to follow a path of wellness inside and out.

This book, divided in 4 chapters, tries to give them the right reply.

Skin retains a large amount of water which looses during its normal process of aging. One key molecule involved in skin moisture is hyaluronic acid (HA) with its associated water-of-hydration. Understanding the metabolism of HA, its reactions within skin and the interactions of HA with other skin components will facilitate the ability to modulate skin moisture in a rational manner.

This interesting topic is focused on this book. Thus the major age-related change is the increasing avidity of HA for tissue structures and the concomitant loss of HA extractability.

Such inter-collated HA may have diminished ability to take on water of hydration and this decreased volume of water give a loss in skin moisture.

An important study for future would be to define precisely the hyaladherins that decorate the HA in

senile skin, and to compare that profile with the hyaladherins of young skin in both the dermal and epidermal compartments. Moreover the increased binding of HA with tissue as a function of age parallels the progressive cross-linking of collagen and the steady loss of collagen extractability with age. Each of these phenomena contributes to the apparent dehydration, atrophy and loss of elasticity that characterizer aged skin.

The science and research behind new active ingredients for aging prevention are opening new doors to novel uses in efficacious personal care products. And the description of many innovative botanicals is widely reported.

Thus the help repair activity of oat β-glucan on skin and hair has been focused together with the weakened mechanisms of immunological defense by some bio-active polysaccharides.

Moreover the *lupine* extract appears to stimulate cellular activity revitalizing keratinocyte differentiation, as a result of its richness in oligosaccharides and low molecular weight peptides; some extracts of *Centella Asiatica* seem able to restore skin firmness and restructure damaged connective tissue.

And *Artemia salina* prepared by marine biotechnologies from specific plankton is characterized by its great capability of withstanding and surviving various sudden environmental aggressions.

The isoflavone genistein activity on skin thickness suggests a positive effect on collagen content and a consequent use for the treatment of UV-stressed skin.

These and others botanicals for balancing cell growth and degradation, to maximize tyrosinase inhibition reducing hyperpigmentation and, to be effective in anti-aging formulations are reported on this book.

However multifunctional natural extracts present an attractive option to formulators seeking to develop innovative products for the anti-aging personal care market. An all-in-one natural ingredient that has the potential to renew recondition, soothe and revitalize optimizers today the new face of natural ingredients.

Therefore formulators working under stringent constraints to strike a balance between natural ingredient compatibility, economics and functionality would find such an option immensely beneficial. For these reasons botanical extracts that support the health, texture and integrity of skin and hair are widely used in cosmetic formulations.

Moreover educated consumer prefers product of natural origin and no longer equates more with better and would rather like to see the scientific rationale behind ingredients in a formulation. And plant materials from which these natural extracts are generally prepared have a long history of traditional *cosmeceutical* use, although the term itself is of recent origin.

Dietary/nutritional supplements can be used to make active nutrients available to all organs of the body. This skin may benefit from active nutrients conveyed by dietary/nutritional supplements. The interrelation between skin and the nutritional homeostasis has been recently highlighted and calls upon the understanding of the cellular and molecular processes in play.

The combining dietary/nutritional supplements and active topical creams both formulated with selected ingredients provide benefits to the skin appearance by reducing visual signs of aging, according with some scientific clinical studies reported on this book.

Working from the *inside out* represents a new and exciting global cosmeceutical approach to supply the skin also through nutrition.

Thus the administration of essential fatty acids (EFA) has been shown to improve and manage skin

conditions, perhaps especially in topical dosage form, but also in oral dosage form.
EFAs are increasingly found in skin-care products, cosmetics and cosmeceuticals, as the benefits of these nutrients become more well-known.
Moreover *gelatin-glycine*, when used both topically and systematically, increases the skin's moisture level and seems able to reduce free radicals in the blood serum and at the skin level. Recent data from human studies provide, finally, evidence that carotenoids, both oxygenated (lutein) and non-oxygenated (β-carotene and licopene), when supplied (topically and by oral route) over a period of several weeks together with vitamin E and vitamin C, protect both the skin against the UV-induced erythema and skin ageing, and the eyes against cataracts and eye related macular degeneration (AMD).
Many others are the studies reported on this interesting book written by different expert scientists known worldwide. In the chapters they wrote they share not only their experience and knowledge but also new information and their views regarding the state of the art and the expected future in anti-aging cosmetics and diet supplements.
Therefore the readers of this book should be cosmetic chemists, dermatologists, biologists marketing managers and all who are interested in knowing in a deeper way the cosmetic composition of the novel anti-aging products and are also interested in formulating either mass-market products or multifunctional prestige product lines.

P. Morganti
Editor-in-Chief

COSMECEUTICALS AND ACTIVE COSMETICS: Drug Versus Cosmetics. Second Edition

by P. Elsner and H.I. Maibach
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Personally I have tried to redefine the term Cosmetic Dermatology in 1995 on the Journal of Applied Cosmetology (13:51-54). At that time, the international medical and chemical communities were unable to determine the real task to be assigned to the field of Cosmetology.

Now Cosmetic Dermatology does not seem to be a paradox anymore as well as the term *cosmeceuticals*, introduced from Albert M. Kligman about 20 years ago. These are the reasons that permitted the tremendous expanding of cosmeceuticals up today.

The second edition of this book testifies this growth with the high number of its chapters grown from 20 to 38 that have been separated into different categories such as classes of cosmeceuticals, raw materials, toxicology, product development, and industry overview.

As Kligman affirms, the term cosmeceutical "serves as a useful function in recognition of the cosmetic industries laudable achievements in bringing to the marketplace a great assay of skin, hair, and nail products which improve the quality of life".

The population of civilized countries is growing rapidly and many are the old ones so the market is following this trend developing antiageing products. Hence a similar growth for the quality of life is needed.

Thus the term *cosmeceutical* has to recognize the new realities of skin care products, emphasizing their functional aspects. New insights about the function of the skin, as well as the development of new products for skin care, make it necessary to redefine the definitions of cosmetic and drugs.

But we don't need new laws.

Aminoacids are molecules with both an amino group and a carboxylic group and at once they are water soluble and amphoteric electrolytes.

Moreover each amino acid has its own role and function in the skin, but more importantly every molecule is interrelated for a harmonized integrity to maintain homeostasis of the skin. This is the reason for the market growth and cost reduction of certain aminoacids for many industrial applications.

The role of these chemicals and their derivatives as functional molecules for cosmeceutical applications are, therefore, particularly focused.

The skin is frequently and directly exposed to a pro-oxidative environment, including ultraviolet radiation, drugs, and air pollutants.

Besides dealing with this external inducer of oxidative attack, the skin has to cope with endogenous generation of reactive oxygen species (ROS) and other free radicals continuously produced during its physiological cellular metabolism. It is generally believed that ROS play an important role in the pathogenesis of several human diseases. To counteract these oxidative injuries of structural lipids and proteins, human skin is equipped with a network of enzymatic and non-enzymatic antioxidant system.

The Stratum Corneum lipid composition and structure together with this antioxidant system plays, in fact, a key role in determining the barrier integrity, which is essential for skin moisturization, normal desquamation and healthy skin condition.

For all these reasons, antioxidants in combination with sunscreens or other photodamage-reducing agents, seem to be highly effective adjuvants increasing the safety and the efficacy of photo protective topical products.

At this purpose there is a growing body of evidence that tea, mainly green tea, and the polyphenols therein content in higher quantity into Italian *espresso coffee* also, possess inhibitory effects against cancer and acts as powerful antioxidant.

We need oxygen to survive but aerobic metabolism in our body generates reactive by-products called *free radicals* which are highly unstable and destructive.

Left unchecked, these free radicals can attack lipids in cell membranes, destroy cellular enzymes, and even damage the genetic material-deoxyribonucleic acid (DNA). If the injury to DNA by free radicals is not totally repaired, the relative damaged is replicated in new cells and slow deterioration that may be responsible for the familiar signs of ageing and the development of heart disease, cancer and cataracts.

The outermost layer of the epidermis, the Stratum Corneum (SC) as part of cutaneous barrier, represents the first protection line from the continuous free radicals' attack from the environment. The damages these barrier layers can undergo during the aging process and their repair is treated on this book, where novel ideas about active ingredients that can be used topically are also discussed.

According with the authors this is an exciting field at the borderline between cosmetics and drugs. Thus a decreased level of intercellular lipids in scalp stratum corneum seems indicating that a barrier defect may be an important factor in *seborrheic dermatitis* and lipids are essential for the growth of *Malassezia furfur*.

And some studies have found an increase of lipids on the skin of patients affected by this disease. However antifungal medical therapy for *Malassezia* is effective in treating most cases of seborrheic dermatitis, such as cosmetic zinc pyrithione shampoos are equally effective.

Therefore many bioactive cosmetics represent the new reality of skincare products and their use should be preferred to the drugs.

Drug development is, in fact, slow and costly, requiring many pre-marketing proofs of safety and efficacy because of their probably side effects. But cosmeceutical claims have not to cross the line distinguishing it from a drug.

Thus cosmeceuticals enable cosmetic scientists to communicate each other regarding the standards that must be met to justify performance claims. At the same time, major producers of active *compounds* have to become more scrupulous in pre-marketing testing for efficacy and safety. When products have been tested *in vitro* and *in vivo* through the dermatological control, they may be classified in my opinion, as *clinically correct cosmetics*, therefore considered cosmeceuticals. This is the

case of some cosmetics based on specific phytosterols, alpha hydroxyacids or UV protective compounds.

Phytosterols, in fact, play a role in plants similar to that of cholesterol in humans and mammals by forming all membranes structures. Thus the use of the extract of *Mimosa tenuiflora* for treating skin wounds and burns, *Ginseng radix* for its antioxidant properties, Rusci aculeati rhizoma for its anti-inflammatory effect or Silene otites for the presence of phytoecdy-steroids, insect molting hormones.

Therefore health improvement preparations are in the market that claims to make the body adaptogenic, possess anabolic actions, and shield the body from stress. This is the reason of the increased demand worldwide for plant-derived chemicals.

For these reasons the interest for the Alpha-hydroxy and Beta-hydroxy acids both in dermatology and cosmetology. These compounds under the presentation of peels and home regimens are recognized as important preventive means and adjunctive therapy in a variety of skin conditions.

Thus the attracted media attention, the consumer curiosity and, the contradictory claims on their proven effects.

As known water is the plasticizer of keratin, allowing the SC layer to bend and stretch, avoiding cracking and fissuring. Furthermore, water increases the activity of enzymes involved in the desquamation process. Water in SC is associated with the hydrophilic parts of the intercellular lipids and with the keratin fibers in the corneocytes.

On the other side dry and chapped skin is a common problem both in health and diseased individuals and not always may be diminished by an increase in skin hydration.

Products used for topical treatment or prevention of dry skin are called emollient or moisturizers.

They are able to break the dry skin cycle and maintain its smoothness. Until now the mechanisms improving dry skin are under discussion. The increased understanding of the interactions between topically applied substances and the epidermis biochemistry together with new instruments which can diagnose specific skin abnormalities will enhance the possibilities to tailor skin care products for various SC diseases.

Photoaging is a life-long process in most individuals, beginning even in infancy and progressing steady until prevention treatment, or death intervenes. The enormous and accumulating volume of scientific and lay literature and the extensive education and public health efforts warning of photoaging have had, at best, modest success in dissuading the general public from their enjoyment of the sun.

Therefore the steady increase in availability of cosmeceutical products which can prevent or reverse photoaging even in occasional claims are less than credible.

However the unstopped rapid advances of science, particularly in the areas of gene regulation will continue to provide pharmaceutical and device products which will be of even greater utility than current cosmeceuticals.

Moreover our knowledge on the relationship between sun and humans and new industrial and commercial activities will guarantee more and more efficacy and safety of sun-products used both topically and by oral route. Thus recently published studies provide evidence that supplementation with carotenoids increases the photoprotective properties both of the topical sunscreens and provides moderate protection against erythema formation.

An emerging trend in cosmeceuticals is the modulation of aging changes by the use of naturally occurring cell regulatory proteins called grow factors. These natural compounds, normally present in tissues, stimulate cell growth, modulate immunity, and orchestrate cell development. Thus, considering their proregenerative effects in wound healing, they should support the modulation of aged and photodamaged skin.

Therefore understanding the four phases of wound healing: homeostasis inflammation, proliferation, and remodeling, will provide a better understanding of the role of some individual grow factors and their interrelationship. The most promising research suggests that multiple growth factors used in combination may stimulate the growth of collagen, elastin, and GAGs.

Thus this probable activity provides a promising first-line treatment for mild to moderate photodamaged skin.

As previously seen, excessive formation of free radicals during the aging process can have damaging effects, particularly at the cell membrane. Dimethylaminoethanol (DMAE), a precursor of phosphatidylcholine, seems to reduce protein cross-linking, a characteristic of cellular aging, by acting as a free-radical scavenger.

Although its mechanism of action is not completely understood, it seems that as a precursor of choline and neurotransmitter of acetylcholine, it acts as an autocrine and paracrine factor triggering effects on skin cells such as keratinocytes and fibroblasts.

This may explain its activity on skin aging signs as wrinkles and sagging.

Skin retain a large amount of water, and much of the external trauma to which it is constantly subjected, in addition to the normal process of aging, causes of loss of moisture.

The key molecule involved in skin moisture is hyaluronic acid (HA). Understanding the metabolism of HA, its reactions within skin, and the interaction of HA with other skin components, will facilitate the ability to modulate skin moisture in a more rational manner. This is because of current research are underwaying to modify HA in such a way to make it more stable and confer very specific properties.

The success of retinoids and hydroxyacids as active ingredients in skin care products designed to improve the appearance of aging skin, has stimulated the search for additional compounds.

A recent addition to this armamentarium is *kinetin* (N6-furfuryladenine), a plant hormone known for growth promoting and anti-aging effects in plant.

This compound seems to act directly as a signaling molecule, involved in signal transduction, stimulating defense pathways such as DNA repair.

Kinetin may also act indirectly as a natural antioxidant, preventing the formation of ROS or as direct free radical scavenger.

Another interesting molecule to be used as cosmeceutical active compound *is melatonin*, better known as regulating the day and the night rhythm depending on light perception of the retina. Moreover it regulates seasonal rhythm concerning reproduction and hair growth in animals, aging, and immunoregulation. Apart from the receptor-mediated hormonal function, melatonin is a strong antioxidative substance active pharmacologically by direct scavenging free radicals as a non-receptor dependent substance.

It also stimulates antioxidative enzymes such as superoxidismutase and is able to suppress free radical formation following UV irradiation.

Detected at relatively high levels in foodstuffs and plants, melatonin has been shown to increase the hair growth activity of follicles, when given orally.
Of considerable cosmeceutical interest are also *heat shock proteins* (Hsp) and *Copper peptide* (GHK-Cu) all both to be used in sun and after-sun care products. On the basis of clinical evidence, the use of Hsp and GH-K-Cu in personal care creams demonstrated to deliver interesting skin benefits. Moreover the use of Hsp in skin ageing therapy seems to be increasingly essential, in order to compensate for loss in skin defense and increase skin comfort toward environmental stress, especially UV stress.
The reported examples are some of the new compounds and new cosmeceutical therapies focused on this second edition of *Cosmeceuticals and Active Cosmetics*.
This new edition is really more interesting and complete than the first one. All the novel molecules used today are reported and discussed, with a plain language, not only from the pharmacological and toxicological point of view but also under the regulatory aspects.
This interesting book should be in the private library of expert biologists, dermatologists, cosmetic scientists, pharmacists, marketing managers, students of medicine and pharmacy and, all the operators involved in Cosmetic Dermatology.

P. Morganti
Editor-in-Chief

FORMULATING FOR SUN

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As known, sunlight and ultraviolet radiation (UVR) from artificial sources can be tonic or toxic to human skin. It is estimated that the incidence of non-melanoma skin cancer in the United States exceeds one millions cases for year, and it is constantly increasing in Europe also.
UV-induced or photo-aging accounts for 80% to 90% of visible skin aging and, UVR damage the skin by both direct effects on DNA and indirect effects on the skin's immune system.
Thus sunlight may be beneficent and life supporting, but we cannot ignore its cumulative effects, manifesting as skin aging and skin cancer. These harmful effects depend upon the duration and frequency of sun exposures, the intensity of sunlight (based on latitude), the seasonal variations, and the reactivity of the skin (based on genetically determined constitutive skin color) which induce pigmentation response of white, light brown, or dark skinned individuals.
Therefore the use of sunscreens that have been shown to reduce the number of actinic or precancerous keratosis and solar elastosis, preventing also immuno-suppression.
Formulating for sun covers in ten chapters a wide range of topics: UV damage in hair and skin forms of delivery and treatments in photo-aging, stability and testing of filters, offering a comprehensive look at the formulation aspect of sun care.
Sunscreens are, in fact, a special class of personal care products containing active ingredients that can absorb UVR to shied skin from the damaging effects of the sun.
The cosmetic formulator has an expanding menu of these active screen ingredients for incorporation into a variety of cosmetic formulations. Selection is restricted by regulatory agencies in the country in which the final product is to be market. Thus some cosmetic formulations may be classified as cosmetic products in Europe and Japan, OTC in USA, Canada and Australia quasi-drugs in China, Korea and Taiwan but in all these countries there is a positive list regulating the active sunscreens to be used.
It means that 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. But apart from the active filters, sunscreen efficacy remains very dependent on vehicle formulation. Solvents and emollients can have a profound effect on the strength of UV absorbance by the active ingredients and at which wavelengths they absorb. Film formers and emulsifiers determine the uniformity and thickness of the film formed on the skiu surface, which, in turn, determines SPF level and water resistance. For products designed to be used while swimming, the film must be waterproof.
Also, care must be taken to minimize the ingredient interaction between the sunscreen active and the

formulation. In some cases, the improper mix of ingredients can result in a significant reduction in the effectiveness of sunscreen active.
Lastly, product aesthetics play a large role in product acceptance, particularly with sunscreens being incorporated into daily-use cosmetics.
Thus the way to use the diethylhexyl-2, 6-naphtalate (DEHN) for increasing the photo-stability of some sunscreens; or the right use of inorganic pigments, as titanium dioxide (Ti O2) and zinc oxide (ZnO) and micronized organic pigment of the benzotriazol family to increase the skin photo-protective activity; or the use of photo-protective polymers, as polyamide-2[a], designed specifically for UVB and UVA protection of hair.
Therefore a variety of formulation vehicles and active compounds that meet all these requirements are reported in this interesting book.
Healthy, shiny hairs start with proper protection and care. Unfortunately hairs are exposed to daily stress, and without proper treatment they will become weakened and appear unhealthy and dull. Moreover artificially colored hair and natural uncolored hair of Asian and Caucasian origin are susceptible to fading upon prolonged exposure to UV radiation.
Polysilicone-15 has the benefits of silicone plus the added benefit of UV protection because the molecule has UV filter moieties attached to the silicone backbone. The silicone provides shine, conditioning and smoothening to the hair while the UV filters provide protection against UV degradation and color change.
This is the poly-functionality required today to sunscreen products also. All these described compounds provide a wide-range of UV- absorption capabilities and ease-of-formulation.
An interesting chapter, dedicated to photo-aging is focused on the treatment of photoaged hands. Meanwhile facial antiaging has always received significant attention, little effort is taken to maintain the health and youth fullness on the back of the hands, which often provide strong clues in determining one's age.
In this case also the use of sunscreens provides antiaging benefits reducing the appearance of the black spots and crepness (skin looseness and luck of smoothness).
However the concentration of UV filters that needs to be used in a sunscreen formulation in order to achieve the desired SPF, is primarily dependent on the composition of the formulation in which they are to be used. Therefore the stability studies of solar protection emulsions and gratification of chemical filters is of great importance.
Thus hydrophobic coating of Ti O_2 and/or organic filters by silicone and dimethicone improve their photo-stability, as well as their dispersion and compatibility in non-polar media.
For all these reasons analytical evaluation of emulsions containing UVA, UVB and IR filters are also reported.
To diminish the destructive effects of UV-induced oxygen radicals, antioxidant is recommended in addition to sunscreens.
Vitamin C (ascorbic acid) is popular but there are problems of photo-stability and it looses its efficacy being easily oxidized. But the study of ascorbic acid in dermocosmetic formulations is important because of its suggested physiological function in the skin. These include its inhibitory effect on melanogenesis, free radical scavenger activity and anti-aging properties. At this purpose the activity and stability of derivatives of vitamin C, as magnesium ascorbate PCA (Pyrrolidone-Carboxilic

Acid) and magnesium ascorbyl phosphate are reported and discussed.
Carotenoids, taken both topically or by oral route, inhibit inflammation linked to sunburn and reduce free radical formation generated by UV radiation. This topic is also reported on the book by a comprehensive study that has measured the changes occurred in various parameters of the skin after oral administration of β-carotene and other carotenoids. By the obtained results it seems that these compounds are able to reduce the sun sensitivity in man.
According with other recent studies carotenoids seems to provide additional sun protection for people who are already using a high-SPF topical sunscreen.
These and other are the interesting topics reported on *Formulating for Sun* a book written for cosmetic formulators but useful also for dermatologists and biologists who desire to have a deeper knowledge on the interesting problem of sun protection.

P. Morganti
Editor-in-Chief

SURFACTANTS: Strategic Personal Care ingredients

By A. J. O' Lenick Jr.
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As known the surface tension of a liquid may be defined as the *work required to increase the surface by unit amount*. Surface tension relatively easy to measure is affected by a number of factors including temperature and the presence of solutes in the liquid. Thus at the surface of a liquid, there exists an attractive force, not balanced by the gas/vapour phase, and therefore molecules are under tension.

As ordinary solutes, to reduce this force-tension, surfactant materials are used.

Most cosmetic products are formulated through the use of these surfactants, as main ingredients, grouped into the following categories: cleaning agents, emulsifying agent, foam boosters, hydrotopes, solubilizing agents and suspending agents.

This book divided in 8 chapters and IV appendices describes physical chemistry, structural attributes, functional properties and analytical tests of the major types of surfactants used for the cosmetic's formulations.

First of all, what is a surfactant?

It is generally a water-soluble compound able, for example, to clean by virtue of its chemical structure. It *surrounds* the fat, with its embedded grime, by forming chemical structures called micelles, so that on rinsing with water, the fat and dirt can be removed from the surface (skin or hair).

There are five main groups of surfactants, distinguished from each other by their chemical structure and electric charge: amphoteric surfactants, anionic surfactants, cationic surfactants, non-ionic surfactants and silicone surfactants.

Different surfactants have different properties and vary in their ability to emulsify or to clean, create lather, and impart lustre or softness, for example, to hair.

But formulators, in the personal care field, realize that there are a vast number of surfactants from which to choose in the preparation of new products.

To understand the salient specifications of different surfactants it's necessary to know not only their chemistry but also the chemistry of potential by-products and residual raw materials content in the final product. *Raw Materials for Surfactants Preparation* is the topic of **chapter 1**.

Amphoteric Surfactants are focused on **chapter 2**. They represent an important class of surfactants also if the consumption of amphoteric surfactants for personal care formulations is relatively low compared with other classes of surfactants.

However there are several members of this class of chemicals whose subdivision is determined by

the ability to support one, two or three types of charges, positive or negative as the pH of the solution changes. True *amphoterics* can exist with anionic (-), cationic (+), or zwitterionic (- and +) charges, depending on the pH.

Ampholytes have a fully quaternized nitrogen and consequently cannot lose their positive charges. As a result, they exist as either zwitterionic or cationic compounds. They cannot exist in an anionic (-) state because the positive charges on the nitrogen are always present.

Moreover amphoterics are compatible with anionic, non-ionic, or cationic surfactants and have extensively used to formulate mild shampoos or as mollifying agents in the more irritating anionic compositions.

A living system, like cells, makes use, in fact, of naturally occurring amphoteric surfactants almost exclusively.

Soaps are salts of fatty acids and, years ago were the mainstay of shampoo products. In soft water they lather copiously, cleanse well, and leave the hair in a well-conditioned style. But, in hard water it deposits on hair a doubling film. Thus, the introduction of synthetic surfactants brought about the end of soap-based shampoos, and fatty alcohol sulphates and their relatives are perhaps the most commonly used class of anionic surfactants.

The inherent property of surfactants to adsorb at interfaces results from their molecular structure.

There are essentially two parts of the molecule firstly a hydrocarbon chain and, secondly, a polar group. The hydrocarbon chain consists of 12 to 18 carbon atoms, while the polar group may be, for example, carboxylate, sulphate or phosphate.

If the hydrocarbon chain is shorter than this, the compound will be lacking in surface activity, whilst a chain which is too long results in the surface active agent having a limited solubility in water. The hydrocarbon chain has an affinity for fatty oils, greases and similar long chain compounds, whereas the attached polar group will have an attraction for water or aqueous solution.

It must be remembered that the hydrophobic group may be of a complex nature and may contain both straight chain and ring compounds. *Anionic Surfactants* is the topic of **chapter 3** where all these surface agents are reported: from fatty alcohol sulphates, sulphosuccinates and phosphate esters, to phospholipids and phosphobetaines.

Because of the negative charge on the surface of hair, cationic strongly bind to hair and are difficult to remove by rinsing. The most important class of cationic surfactants is referred to *as quats* divided in four major groups:

Alkyl quats, alkylamido quats, polymeric quats and imidazoline-derived quats.

Despite the fact, these materials have been recognized as key cosmetic additives, there is little published on the structure function relationship on basic properties. For example, some quats are very insoluble when added to anionic surfactant, other have improved compatibility. The ability to select quats that have optimum compatibility with anionic systems offers the formulator flexibility in formulating heretofore unavailable.

Therefore background, chemical and physical properties and purposes of quaternum compounds are reported on **chapter 4.**

Non-ionic surfactants are preferable to those that are anionic, but here found limited use owing to poor foaming capacity for shampoos.

Alkanolamids and alkyl amine-oxides are the major classes of non-ionic surfactants used primarily as foam boosters and stabilizers. They stabilize the foam and, depending on the kind, provide con-

ditioning effects on hair and skin.
Of great interest are the alkylglucosides and alkypolyglycosides (APG's) derivatives that may be obtained through reaction of fatty alcohol with glucose.
It is very difficult to find a comprehensive study of APG's, and yet, this class of fatty alcohol derivatives is gaining tremendous momentum as both a finished product and a more recently, a very desirable raw material.
Chapter 5 is focused on the *new trends* of these and other interesting skin friendly compounds generating benefits both on skin and hair.
What is to remember is that non-ionic surfactants do not dissociate into ions in aqueous medium. They are appreciated for their good skin and eye compatibility as well as for their anti-irritant potential when they are combined with anionics in appropriate concentration ratio.
Therefore, numerous products for sensitive skin, babies or the face incorporate non-ionics as major surfactants.
Surfactants, which can be classified in the chemical group of organ-silicones, are structurally derived from polydimethylsiloxanes, in which some methyl are replaced by hydrophilic groups that can be anionic, cationic, amphoteric or of non-ionic nature.
These silica-based surfactants provide conditioning, softening, irritation mitigation, barrier properties and emulsification. And many of these desirable effects are not achievable in all kind of formulations using traditional surfactants or silicone fluids.
Moreover, for example, some silicone compounds as alkyl dimethycone copolyols, provide advantages over traditional hydrocarbon chemistries because they can be used in the preparation of emulsions without heat. These silicone polymers can be used to prepare products that contain little wax, a large concentration of water and have a light spreadable feel on the skin.
All the classes available of silicon-based surfactants are reported on **chapter 6.**
Surfactants are not pure chemical species.
As such, they are correctly described as compositions, not compounds. All surfactants contain traces of raw materials and some concentration of by-products of the reactions, such as inorganic salts. Many contain solvents, such as water, other contain additives that alter their performance.
Therefore, determining how a chemist analyzes the surfactant that he or she purchases commercially is an important matter.
And **chapter 7** gives the reader an overview of what the various analytical methods are and why are of importance in establishing specifications and test methodologies for surfactants.
By this chapter the chemist may understand the kind of analysis to employ for a specific surfactant and tailor an analytical regimen for the chemistry of the surfactant chosen.
Interesting also is **chapter 8** that reports many *Patent References*.
Patents are probably the single most important source of information on the basic synthetic processes and technology used in the preparation of surfactants.
In addition to technology available for public use in expired patents, a review of patent literature gives the chemist an understanding of how the creative process works. And this interesting chapter is focused on some important patents covering surfactant technology, illustrating examples of the valuable technical and historical information contained in patents.
The book ends by four interesting and practical *Appendices* reporting description and how to apply the *Three-Dimensional HLB System (Appendix I), Surfactant Interaction with Skin (Appendix II),*

Analytical Methods (Appendix III), and unusual *Instruction for using pellet Press.*
Today silicone-soluble material is an important aspect of emulsion technology.
A growing number of silicone-based surfactants contain no hydrocarbon-based hydrophobes. Other silicone-containing surfactants also contain hydrocarbon groups. Therefore formulators need an expansion of the traditional hydrophilic/lipophile balance (HLB) concept capable to work not only with water and oil, but also with these new surfactants and anhydrous systems.
And at this purpose it has been designed an HLB system that consider oil, water and silicone solubility to determine the emulsion properties of surfactants. This is the *Three-dimensional HLB* reported and described in these Appendices.
Many are the existing books reporting the organic and physical chemistry of the different kind of surfactants. But this agile and well written book by Anthony J. O'Lenick Jr., I personally met this year in Milano, has the merit to be very clear and understandable.
It has to be considered a useful and not replaceable mean of study for Cosmetic Chemists who wish to control the functional properties of all the used surfactants in its daily work. Hence it is an excellent source of knowledge, an ideal reference, as well as an experimental laboratory guide for pharmacists, manufacturers of cosmetic and students in chemistry who wish to understand deeper the structure attributes and functional properties of old and new surfactants.

P. Morganti
Editor-in-Chief

LATEX INTOLERANCE. Basic Science, Epidemiology and Chemical Management

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An estimated 2 to 10% of the general population is affected by hand dermatitis. It appears to be the most common occupational skin disease comprising 9 to 35% of all occupational disease and up to 80% or more of all occupational contact dermatitis.

But what is the occupational skin disease?

It is a cutaneous disorder caused by toxic factors primarily associated with the workplace. Key elements of this definition include the recognition of high-risk skin conditions, identification of causal toxins, and determination of the probability of exposures in a given work environment.

The spectrum of toxic factors leading to the expression of occupational skin diseases may be classified as chemical, mechanical, physical and biological. Another defining component of an occupational skin disease is that there must be workplace exposures that account for clinical findings. Examples include chemicals that trigger facial dermatitis among workers handling and mixing volatile epoxy resin-based paints and airborne fiberglass causing a popular eruption among sanders of molded plastic. Health care workers are the occupational group consistently reported as having the highest rates of sensitization to latex.

Rates of type I sensitization in this group are reported between 2 to 17%. Other groups which may be affected are domestic workers, and hair dressers.

The most common source of occupational exposure is gloves made from natural rubber latex. And *Latex intolerance* is the general topic of this book consisting of 22 chapters.

A fundamental understanding, of the pathogenesis of latex allergy is essential to be able to diagnose and manage the condition. As a matter of fact, many individuals who test positive with either of usual methods do not have no-chemical history compatible with allergy nor can a positive response be demonstrated on allergen exposure.

Therefore these individuals are best defined as sensitized rather than allergic. Thus it is clear that the symptoms of latex exposure are not, in many cases, sufficiently reliable to allow a confident diagnosis of latex allergy. Moreover knowledge of the whole spectrum of clinically relevant natural rubber latex (NLR) allergens will help researchers to develop more specific *in vivo* and *in vitro* tests for diagnostic purposes and, the production of pure allergens could provide tools for immunotherapy. Further study is needed in many areas to increase our understanding of latex allergy and to extend the benefits of allergy prevention strategies to the widen population. Further refinement of investi-

gative techniques will help separate those that are sensitized from those that have clinical allergy. This topic is focused on **chapters 1** and **2.**

Encouraging evidence now suggests that strategies that limit the use of latex gloves to powder-free low protein brands may be reducing the incidence of occupational sensitization to latex. Thus the search for gloves that minimize the risk of glove-associated reactions has increased the production of alternatives to natural rubber. Unfortunately, both natural and synthetic rubbers have the ability to cause both allergic and irritant reactions.

Chapters 3 to **5** reviews the chemical composition and manufacturing permutations of natural and synthetic rubbers necessary to better understand the pathogenesis of latex allergy/sensitization. Progress in testing could not occur prior to acquiring sufficient knowledge about properties and structures of numerous unidentified allergenic proteins. And accuracy of the test for quantification of allergens in NRL products is even more critical, as this would represent a direct and only measure of the potential risk for sensitization or allergic reaction.

Current approaches to measure individual allergens using monoclonal antibodies are quite specific and accurate. However, the evaluation of each test sample separately for each of the major allergens would be impractical, time consuming and expensive.

The prevalence of NRL allergy seems to be increasing, and it is considered to be a serious medical problem for a number of patients and health care workers. Thus regulatory agencies and consumers have suggested improving the identification of potential chemical allergens. When assessing gloves in terms of their potential to cause glove-associated reactions, European Union (EU) Directives can provide some guidance.

In Europe, disposable gloves are classified according to Council Directive 93/42/EEC for Medical Device Directive (MDD) or Council Directive 89/686/EEC for Personal Protective Equipment (PPE) whereas MDD does provide some requirements for minimizing glove-associated reactions, this does not appear to be the case for PPE.

Specifically MDD requires that the protein content of latex gloves does not exceed 50 mm of total water extractable protein per gram (EN 455-3) and all gloves have undergone the 200 person Modified Draize Test to demonstrate low irritant or allergic contact dermatitis potential (EN ISO 10993-10) according to the requirements for the biocompatibility of MDDs as required by 93/42/EEC.

Thus minimizing allergen concentration in latex gloves to prevent sensitization and the development of clinical allergy to NRL is acknowledged to be of natural interest for rubber manufacturers and regulatory health authorities.

At this purpose new accurate and specific methods to measure the allergic potential of NRL goods have been developed. The new assays are usually based on the capture-enzyme immunoassays (EIA) principle and on the use of monoclonal antibodies and purified or recombinant allergens.

This new method, discussed on **chapter 6**, could eventually lead to specific guidelines for the rubber industry and regulatory health authorities.

Contact Urticaria, skin disease of increasing importance, is focused on **chapters 7**, **8** and **9** where syndrome, prognosis and related chemical manifestations are reported and discussed.

This disease is a localized wheal and flare reaction following external contact of a substance with the skin and or mucous membranes. Contact urticaria usually appears within 10 to 30 min and clears

completely within hours, without residual signs of irritation. However it needs to be distinguished from simple irritant symptoms or glove *itch* which is frequent among health care workers who wear gloves for prolonged periods, especially if there is any associated hand dermatitis.
However *allergic contact dermatitis and contact urticaria* have been associated with latex intolerance, and irritation has been less well studied.
Unlike allergic contact dermatitis, irritation is due to non-immunological factors. Thus all forms of contact dermatitis are inflammatory in nature and are caused by direct skin exposure to an offending chemical: a sub class of these disorders requires the presence of ultraviolet light to produce a reaction.
The term irritant contact dermatitis is used when the causative chemical injures the skin directly. Therefore chemicals include mild soaps, detergents, and solvents that damage the skin by repeated contact, as well as alkalis and acids that can produce blisters and ulcers after a single exposure.
Allergic Contact Dermatitis (ACD) to rubber classically occurs to the low molecular weight chemical additives, such as thiurams and thiazoles and not to the high molecular weight isoprene protein, its principal component. All these problems are discussed from **chapter 10** to **15**.
Any individual disabled in the workplace is a loss to the society, in terms of human suffering and also a waste of large amount of resources in euro and in lost productivity. The medical profession has the responsibility to help make the occupational environment safe and healthy : the health and safety of the individual in the workplace should be accorded the highest priority.
Chapters 16, **17** and **18** offer practical instructions for patients to follow and give the background studies and evidence base from which these recommendations are drawn. These suggestions are summarized and simplified in an information sheet that can be given to the patient to reinforce the individual points made during the consultation. It is also reported the main treatments, such as moisturizing cosmetics and barrier creams, the physician has to consider when managing a patient with hand dermatitis. However topical corticosteroids remain a mainstay of therapy, but corticosteroids can also be allergens. Contact sensitivity may be elicited by components of the vehicle or by the corticosteroid itself. Cross-reactions among groups of corticosteroids and flares with systemic steroids may complicate therapy. Poor penetration of the stratum corneum is a particular problem with hydrocortisone also, meanwhile occlusion increases the percutaneous absorption.
In conclusion medical gloves are an important part of a clinician's personal protective equipment and are highly regulated medical devices. Regulations will continue to evolve to put even greater emphasis on user safety.
As new materials for medical gloves are developed, standards will need to reflect the unique properties of specific materials and will help clinicians select the right gloves for the right reasons. In addition, learning to recognize sources of rubber allergens and ways to avoid them, medical workers must be educated about the importance of skin health, type I and type IV allergy symptoms, and the chemical content of other products to which they and their patients may be exposed.
In fact, all physicians including medical, surgical, and dental practitioners must be aware of the impact of natural rubber latex (NRL) allergy on chemical practice, both in terms of prevention and emergency management. It is important to appreciate that NRL allergy may initially present with local symptoms only and develop more serious systemic manifestations with subsequent exposure.
The conclusions of the last four chapters can be summarized in these must: prevent exposure throu-

gh engineering control, substitute gloves with less irritating chemicals, enforce personal protection, educate, and institute pre-employment and period screenings. In fact attributable risk depends both on the degree of irritation and frequency of exposure.
Prevention of exposure to a weak but frequent irritant can have more profound effects than removal of a strong but infrequently contacted irritant. Gloves of ethylene vinyl alcohol copolymer sandwiched with polyethylene are effective against epoxy resin, methyl methacrylate, and many other organic compounds. But when seeking alternative to latex, it is important to remember that powdered synthetic gloves should be avoided to reduce the risk of irritant and allergic contact dermatitis.
This interesting book provides a comprehensive coverage and has to be considered a reference source of latex allergy for dermatologists, individuals working in dentistry, plastic surgeons and medical professionals using gloves for their daily work especially when they have to manage patients affected by latex intolerance.

P. Morganti
Editor-in-Chief

PROTECTIVE GLOVES FOR OCCUPATIONAL USE. Second Edition

by A. Boman, T. Estlander, J.E. Wahlberg and H.I. Maibach
2005. 368 pages. Hardcover
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Occupational dermatoses in health workers are difficult to classify because there are many professions in which the risks are very different, and one can find dermatoses not only of chemical origin (irritant and allergic), but also of infections and physical origin.

About irritant dermatitis the incidence can be high among nurses and surgeons, because of the use of many antimicrobial products and the frequent washing of hands.

In addition, sensitization to latex, particularly allergic contact urticaria is frequent, resulting in serious repercussions among this group of personnel. Thus most cases of contact dermatitis in the health profession involve, the hands.

The variety of insults to the hands include frequent exposure to detergents, medications, gloves, and chemicals unique to the profession. Among the most allergenic chemicals are antimicrobials and acrylates. Therefore more than 90% of occupational skin diseases are diagnosed as irritant or allergic contact dermatitis. Forty to sixty percent of all individuals who wear gloves experience the most common form of dermatitis (non-allergic irritant contact dermatitis) at same time.

The next most common form type IV contact dermatitis, accounts for most glove-associated allergic reactions.

Type I latex sensitivity varies depending on the test method used (a serum assay versus a skin prick test) but isolated location studies suggest sensitivities that range from less than 1% to more than 6% of the general population, 3-5% of general hospital personnel and 10-15% in the operating room.

Therefore people in the biotechnology, medical device and pharmaceutical industries wearing gloves more often and for longer periods of time, reporting incidents of irritant contact dermatitis, allergic contact dermatitis (Type IV) and immediate type hypersensitivity (Type I) have increased dramatically.

Along with escalating glove use, variability in manufacturing processes, frequent glove changes, constant hand washing and the use of powder have potentially contributed to the development of these sensitivities and continue to do so.

For all these reasons despite the growing numbers of reported glove-associated reactions and many diagnosis confusing, this book may certainly allow the reader to learn how to distinguish the three types of reactions, how to identify who is at risk of sensitization and how to manage sensitivities.

Divided in 22 chapters, it focuses on protection from chemical and biological agents and on adver-

se reactions caused by protective gloves, highlighting some specific causes and general symptoms of irritant and allergic contact dermatitis and latex allergy.
The value of disease prevention is evident to individuals, society, and the medical community. For human, social, and economic reasons, it would be of great benefit if people exposed to harmful chemicals and products could be protected from developing contact dermatitis.
Thus the use of protective gloves is one of several possibilities to avoid developing a contact dermatitis or a relapse also if current protective gloves do not provide the promised protection. However prevention of work-related diseases and injuries affecting the skin requires an assessment of the hazards and the risks associated with performing the work prior to the assignment of protective clothing or requirement.
This assessment, legally required in some communities, is typically called a hazard or risk assessment. Therefore knowledge of the hazard and how to use properly protective equipment not only reduces risk but also provides the health and safety professional with a worker capable of contributing feed back on the effectiveness of the protective equipment. And gloves made of rubber and plastic materials, is an essential factor in order to prevent or reduce direct skin contact to harmful agents. But its *protective effect* against hazardous agents is depending on several factors, such as material formulation, manufacturing process and control exposure to chemical mixtures etc.
It is therefore important to choose gloves that have proved to fulfill appropriate quality control testing. All these interesting themes are focused on **chapters 1, 2** and **3.**
Despite the use and nonuse of gloves, hand injures continue to be one of the most frequently reported occupational injures, that are preventable if the correct gloves are selected and used for protection against hazard.
Selection of gloves for occupational use is the job of the safety professional. Thus guides, regulations and standards for glove use have become available in the more organized country as EU, USA and Japan.
These rules are reported in **chapters 4,5** and **6**, where stringent quality standards for medical products are maintained so that they may be considered safe and effective.
The use of protective gloves is of crucial importance in workplaces where hazardous chemicals are handled. Thus the skin protection from a glove depends on several factors such as barrier function of the glove whether or not the material is affected by the substance during use and whether the glove is sensible. The time span the glove will be stored, how the glove is stored before use, and how long is used are other factors that might influence its protective effect.
Therefore national and international standards have been developed to achieve reproducible results in testing gloves for efficacy. And many testing procedures and quality control testing are reported and discussed on **chapters 7, 8** and **9**.
Clearly, glove-related allergy has been a problem for health-care workers worldwide, but protective gloves can also mean that already sensitized individuals might be able to stay at work. This is of great benefit not only to the individual but also to be community.
Inevitably the search for gloves that minimize the risk of glove-associated reactions may lead to consideration of alternatives to natural rubber latex. When considering alternatives, it should be noted that natural rubber gloves have set the standard in the past regarding barrier protection, comfort, durability and cost. Therefore, an alternative glove material should not compromise the excellent

characteristics hither to enjoyed with latex.
In this respect, vinyl or polyvinyl chloride (PVC) may seem an attractive option on cost grounds, but they do not share the same level of strength, elasticity and barrier protection properties as latex has. Therefore when seeking alternatives to latex, it is important to remember that powdered synthetic gloves should be avoided to reduce the risk of irritant and allergic contact dermatitis.
Apart from the negative aspects of powder as an irritant and a vector for chemical and protein allergens, powder has the potential to contaminate laboratory samples of assays producing inaccurate test results. Thus the appropriate gloves should be selected to provide varying degrees of protection to specific *irritants and allergens*, reducing also the risk of sensitization.
As a matter of fact protective gloves often come in contact with damaged or inflamed skin, which conditions may have been induced by previously encountered contact allergens or, more likely, by irritants undoubtedly associated with various professions (hairdressing, housekeeping, medical and paramedical). Hence, the potential glove allergens penetrate more easily into the damaged skin than would otherwise be the case, thus giving rise to sensitization.
When chemicals penetrate the gloves, the risk of sensitization is increased, in fact, because of the occlusion effect. Therefore, information about penetration rates and the development of suitably safe products are necessary for people who works with hazardous chemicals. Moreover, the risks should be analyzed, and appropriate gloves should be selected.
In addition, occlusion enhances skin hydration and increases percutaneous absorption. Thus it compromises skin barrier function by impairing passive transepidermal water loss at the application site and hence aggravates the irritant effect of applied compounds. However, such reactions can be minimized by approaches such as immunosuppressive agents, antioxidants, local anaesthetic, and other anti-irritant technologies. Application of optimal hydrocolloid patches that absorb water in both liquid and vapor form can also decrease the irritant reaction.
All the adverse effects of protective gloves are discussed on **chapters 10** to **16**.
As previously described gloves and other protective clothing are designed either to protect the environment from the person, such as in semiconductor manufacture, or to guard the body from environmental insult. At this purpose there is an enormous range of chemical protective gloves available. These differ in design method of fabrication, and in the materials used to provide the protection against chemical insults.
Thus the health protection goals for gloves may focus on two purposes: to prevent localized damage of the skin from irritant, corrosive, or other harm or to limit the systemic uptake of chemicals through the skin.
In chapter 17 the methods available to measure dermal exposure are discussed and the relative studies that help clarify the effectiveness of gloves are presented.
By the available measures of external exposure is possible in fact, to estimate uptake of chemicals with and without the protective gloves.
Millions of gloves are worn every day around the word in an attempt to protect workers from chemical hazards.
Unfortunately, in all too many cases the protection that employer and employee believe the gloves provide is not achieved.
The **chapters** from **18** to **22** detail selection instructions that will make it easier for workers in spe-

cific areas to choose protective gloves. Since gloves are a health risk to the skin by themselves, they should be worn only in situations where they are needed. Thus they should always be used when chemicals are handled in a way that creates same kind of health risk and when technical protection procedures fail to provide sufficient protection.
Moreover it is necessary to know what kind of gloves can give protection against the chemical used, and how the gloves should be used to provide the protection.
As a matter of fact, gloves can also reduce the spread of microorganisms from personnel to patient during surgical procedures being used in operative theaters as well as in wards and laboratories. Therefore to meet the varying needs in different health-care settings, availability of a wide selection of high-quality gloves made of different materials is of the utmost importance.
Finally education, training, and supervision are almost as important elements in the preventive strategy to reduce exposure, as the correct glove for the relevant task.
The practice of occupational dermatology, in its widest sense, is a specialty within a specialty because the physician must be a dermatologist as well as an engineer, a chemist, and an expert in labor relations, insurance regulations, and medical-legal aspects of this problem.
However he must not lose the humanitarian incentive and must recognize that the complete scope of this work is not only treating a patient in relation to his or her job, co-workers, and environment. Moreover, the increase in glove-related sensitivities correlates closely with the increase in glove use. Prevention through reduced exposure is of paramount importance. Choosing low protein (for latex gloves), low chemical, powder free gloves is the first step to managing glove reactions.
For all these reasons and for all the occupational problems reported, this book will be useful, first of all, for those dermatologists involved in chemical research and product development in connection with cosmetic and pharmaceutical chemists. It will be also a valuable resource for occupational health physicians and nurses, plastic surgeons and all the medical and chemical community who work in the fields where skin exposure may occur.

P. Morganti
Editor-in-Chief

COMPLESSO INTEGRATO COLUMBUS

II CORSO DI AGGIORNAMENTO IN
DERMATOLOGIA CLINICA E COSMETOLOGICA
per dermatologi e medici di base

"LE NUOVE TERAPIE EMERGENTI IN DERMATOLOGIA"

Roma, 29 – 30 Settembre 2006

MÖVENPICK
Hotels & Resorts

Via Moscati, 7- 00168
Roma

INFORMAZIONI GENERALI

SEDE DEL CONGRESSO Hotel Movenpick, Via Moscati, 7- 00168 Roma

DATA 29 e 30 settembre 2006

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ATTESTATO DI PARTECIPAZIONE
Alla fine del Congresso un attestato di partecipazione verrà rilasciato in sede agli iscritti che ne faranno richiesta.

ACCREDITAMENTO ECM
E' in corso la registrazione per il programma nazionale di Educazione Continua in Medicina (ECM) presso il Ministero della Salute. I partecipanti interessati sono pregati di ritirare la documentazione necessaria presso la Segreteria Congressuale.

SCHEDA DI ISCRIZIONE
La scheda di iscrizione al Congresso, acclusa al presente programma, dovrà essere resti-tuita alla Segreteria Organizzativa debitamente compilata ed accompagnata dal versa-mento della relativa quota.
Quota di Iscrizione (IVA Esclusa) Entro il 31.08.2006 Euro180,00
Dopo il 31.08.2006 Euro 200,00

Scheda di Iscrizione al Congresso

Nome *		Cognome *	
Via-Piazza *		C.A.P.	
Città *		Stato *	ITALIA
Telefono *		Fax	
Tel. Portatile		E-mail *	

Istruzione

Diploma	
Laurea	
Specializzazione	

Dati Fatturazione

Intestazione *			
Via-Piazza *		C.A.P.	
Città *		Stato *	ITALIA
Codice Fiscale *		Partita I.V.A. *	

☑ Quota d'iscrizione entro il 31 agosto 2006 — Euro 180,00
Quota d'iscrizione in loco — Euro 200,00

Informativa per Trattamento di soli dati personali comuni

☐ Acconsento, ai sensi della vigente normativa, a che i dati da me forniti siano inseriti in un indirizzario al solo scopo di ricevere informazioni sull'attività congressuale.

L'iscrizione al Congresso si può effettuare mediante:
Pagamento con Bonifico Bancario
Effettuare il bonifico intestato a: Congress Service Srl Dermatologia, Banca Credito Bergamasco, Viale Civiltà Del lavoro 64, 00144 Roma - Agenzia Roma Eur C/c 3494 Abi 3336 Cab 3208 cin J

Compilare la "Scheda di Iscrizione al Congresso" allegata al programma e inviarla debitamente compilata insieme alla copia del bonifico bancario e dati relativi alla fatturazione via fax al Numero 06.3052353.

- **Pagamento con Assegno di C/C**

Intestato a: Congress Service Srl
Dermatologia

Compilare la "Scheda di Iscrizione al Congresso" allegata al programma e inviarla debitamente compilata insieme all'assegno di C/C alla presso la con i dati relativi alla fatturazione Centro Ricerche Cosmetologiche
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Per ogni ulteriore informazione è possibile rivolgersi alla segreteria organizzativa al numero 06/30155143.

ADRITELF

Università degli Studi
di Catania
Dip. di Scienze Farmaceutiche

XX Simposio
A.D.R.I.T.E.L.F.

Associazione Docenti e Ricercatori Italiani di
Tecnologie e Legislazione Farmaceutiche

La Tecnologia Farmaceutica nell'Università e nell'Industria

Hotel Baia Verde 4-7 Ottobre 2006
Catania

Programma Preliminare

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PROGRAMMA

Mercoledì 4 Ottobre - (Palazzo dei Benedettini)

ore 16.00 Registrazione dei partecipanti
ore 18.00 Saluto ed apertura dei lavori
ore 18.30 Conferenza plenaria
ore 20.00 Cocktail di benvenuto

Giovedì 5 Ottobre - (Hotel Baia Verde)

ore 9.00 Conferenza Plenaria
ore 10.00 Coffee break
ore 10.30 Presentazioni Orali
ore 13.00 Colazione di lavoro
ore 14.30 Sessione Poster
ore 15.30 Presentazioni Orali
ore 17.00 Coffee break
ore 17.15 Presentazioni Orali
ore 19.00 Visita al centro di Taormina - Serata libera
ore 23.00 Rientro in albergo

Venerdì 6 Ottobre - (Hotel Baia Verde)

ore 9.30 Conferenza Plenaria
ore 10.30 Coffee break
ore 11.00 Sessione Poster
ore 13.00 Colazione di Lavoro
ore 15.30 Presentazioni Orali
ore 17.00 Coffee break
ore 17.15 Assemblea A.D.R.I.T.E.L.F.
ore 20.30 Cena Sociale

Sabato 7 Ottobre - (Hotel Baia Verde)

ore 9.30 Tavola Rotonda
ore 11.00 Conclusione del Simposio
ore 12.00 Visita alla Villa del Casale (Piazza Armerina)
ore 17.00 Rientro in albergo

INFORMAZIONI SCIENTIFICHE

Gli abstract delle Presentazioni scientifiche e dei poster devono pervenire alla Segreteria Scientifica entro e non oltre il 10 Giugno 2006. Gli Autori saranno informati dell'accettazione. La presentazione dei contributi orali e poster e la relativa pubblicazione sul volume degli atti congressuali sono subordinate all'iscrizione di almeno uno degli Autori.

Poster

I poster devono avere una dimensione massima di 80x110 cm. Dovranno essere affissi entro le ore 10.00 del giorno prefissato e rimanere esposti per l'intera durata della sessione.

Presentazioni Orali

Per le presentazioni orali, potranno essere utilizzati file in formato elettronico (preferibilmente MS PowerPoint).

Attestato di Frequenza

L'attestato di partecipazione sarà rilasciato dalla Segreteria Organizzativa al termine del Convegno.

INFORMAZIONI GENERALI

Sedi del Convegno

Mercoledì 4 Ottobre (16.00-19.30) presso:
Aula Magna del Palazzo Centrale dell'Università,
Piazza Università 2, Catania.

Tutte le altre attività congressuali avranno luogo presso il Grand Hotel Baia Verde,
via Angelo Musco 8/10, 95020 Cannizzaro (CT).

Sistemazione Alberghiera

Le informazioni relative alla prenotazione alberghiera saranno comunicate con la seconda circolare.

QUOTE DI ISCRIZIONI

La quota di iscrizione comprende:
La partecipazione alle sessioni scientifiche, gli atti del convegno, il cocktail di benvenuto, i coffee break, le colazioni di lavoro, la cena sociale e la visita guidata a Piazza Armerina.

La quota degli accompagnatori comprende:
Il cocktail di benvenuto, i coffee break, le colazioni di lavoro, la cena sociale e la visita guidata a Piazza Armerina.

Il dettaglio delle attività sociali sarà riportato nella prossima circolare.

	entro il 10.06.2006	dopo il 10.06.2006
Soci ADRITELF e AFI	€ 450,00	€ 550,00
Non soci	€ 550,00	€ 650,00
Dottorandi e Studenti	€ 300,00	€ 400,00
Accompagnatori	€ 300,00	€ 400,00

(IVA 20% inclusa)

Annullamenti
È previsto un rimborso del 70% sulle quote versate, solo per annullamenti pervenuti alla Segreteria Organizzativa entro il 20 Luglio 2006. Dopo tale data non è previsto alcun rimborso.

CENNI STORICI E PAESAGGISTICI

Catania, "la città dell'elefante", è la seconda della Sicilia, adagiata sul mare Ionio ai piedi del vulcano Etna. Secondo Tucidide, sarebbe stata fondata da coloni calcidesi nel 729 a.C., con un primo insediamento sull'acropoli della città, dominata oggi dalla chiesa di S. Nicolò e dal grandioso convento dei Benedettini. E' una città fondata sulla lava, rinata dopo l'eruzione del 1669 e interamente ricostruita dopo il terremoto del 1693. Il suo stemma è un elefante di lava, posto ad ornamento della fontana monumentale di piazza Duomo. Nel 263 a. C. cadde nelle mani dei Romani. In seguito alle invasioni barbariche subì il dominio gotico da cui si sottrasse nel 535 d.C. Catania fu incorporata nell'impero bizantino per tre secoli fino all'invasione araba, che larghe tracce lasciò nel patrimonio linguistico e nell'introduzione di alcune colture. Catania conobbe la dominazione Normanna con Federico II di Svevia, che ne fece una città regia su cui fece incombere la mole minacciosa del Castello Ursino. Con gli Aragonesi Catania ritornò in auge; fu sede del **Siciliae Studium Generale**, l'Università, la più antica dell'isola, fondata nel 1434 da Alfonso il Magnanimo. Successivamente seguì la dinastia Borbonica. L'interesse monumentale e architettonico ruota attorno agli edifici della ricostruzione del XVIII secolo. La Cattedrale in piazza del Duomo, realizzata nel 1736, è dedicata a S.Agata e fu costruita sui resti delle romane Terme Achilleane tra il 1078 e il 1093. L'attuale città sorge ai piedi del più grande vulcano attivo d'Europa, che è il perno geologico della Sicilia Orientale. La sua superficie di oltre 50.000 ettari ha caratteristiche particolari, con un ecosistema unico. Al di là delle spettacolari e a volte devastanti eruzioni, il vulcano è considerato dai catanesi come una madre generosa che dispensa fertilità e scuotimenti psicofisici spesso benefici. L'immagine terrificante della sua potenza distruttrice non offusca la bonarietà e gentilezza del suo microclima. L'attività del vulcano risale a 700 mila anni fa, nel Pleistocene cominciò a colmare l'area del golfo fino all'altezza attuale di oltre 3350 metri.

Note [redacted]

In copertina / Front cover

Cellule Neuro 2 A trattate con H_2O_2 e BETAEFFE PLUS 0,5 μg/ml (immunofluorescenza con phalloidin, x100). *Su gentile concessione* della Prof.ssa Graziella Biagini, Istituto di Morfologia Umana Normale, Università Politecnica delle Marche, Ancona, Italia

Neuro cells 2A treated with H_2O_2 30μM and BETAEFFE PLUS 0,5 μg/ml (immunofluorescence with phalloidin, x100). *On kind permission of* Prof. Graziella Biagini, Istituto di Morfologia Umana Normale, Università Politecnica delle Marche, Ancona- Italy

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