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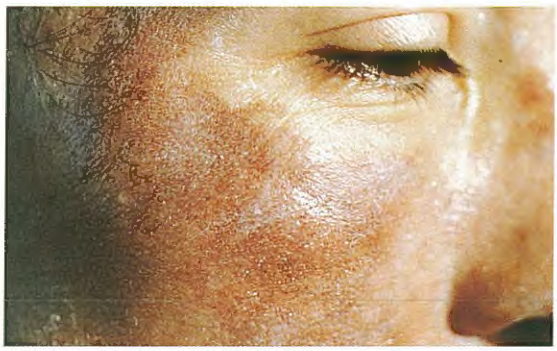

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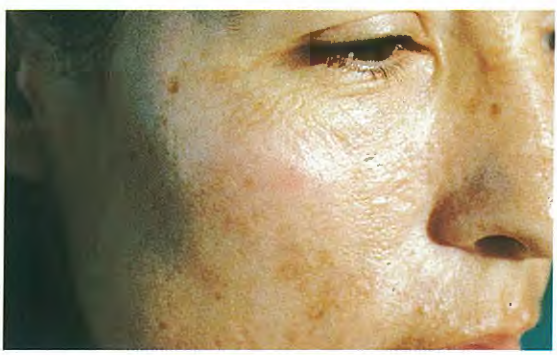

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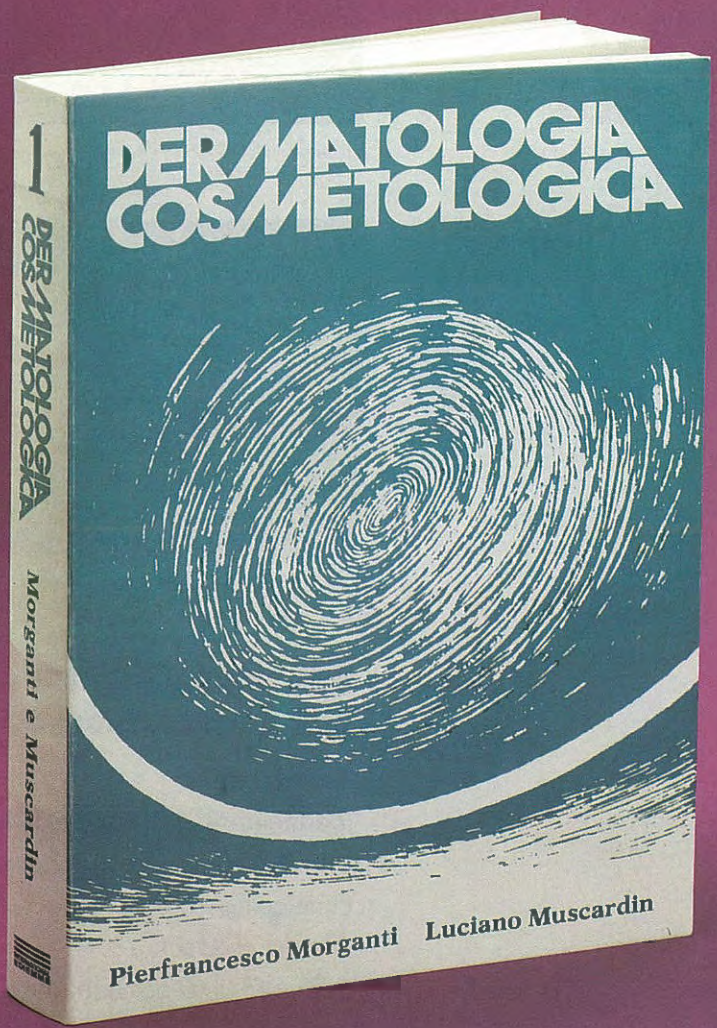

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THE PROTECTIVE AND HYDRATING CAPACITY OF EMOLLIENT AGENTS IN THE ANTI-AGING TREATMENT OF THE SKIN

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Professor of skin pharmacology and cosmetic chemistry,
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Received: *March 30, 1993. Presented at the Nordic Symposium "Focus on the antiaging treatment of the skin", Oslo, March 24, 1993*

Key word: *Skin Hydration; Emollient Agents; AHAs; Photoaging; Tretinoin; Cutaneous Biotype; Skin Homeastasis.*

Synopsis

The skin is uniquely structured to function as a major barrier to protect the underlying organs against the ravages of the enviroment. With age, the dermal structural fibers change their nature and their organization so that their solubility decreases and various physical properties alter. In Cosmetic Dermatology, moisturizing creams are used to solve the cosmetic problem of dry, dehydrated and aged skin. These creams are made up of a set of lipids, water and different kind of active compounds. The aim of so-called emollients and moisturizers is not only to act as simple lubrificants, but to maintain skin homeostasis.

Riassunto

La pelle è una struttura appositamente organizzata per funzionare come barriera protettiva per gli altri organi nei confronti dell'ambiente. Con l'età, le strutture del derma modificano la loro natura e la loro organizzazione in modo da diventare meno solubili e quindi meno attive. Nella Dermatologia Cosmetologica, si utilizzano le creme idratanti per risolvere il problema cosmetico che si crea come conseguenza della cute secca, disidratata ed invecchiata. Queste creme sono formulate come miscele di lipidi e acqua con diversi e specifici principi attivi. Lo scopo dei cosiddetti "emollienti" ed "idratanti" è quindi di agire non soltanto quali semplici lubrificanti, ma di mantenere l'omeostasi della pelle

The skin as barrier

The skin is uniquely structured to function as a major barrier to protect the underlying organs against the ravages of the enviroment. The epidermis mantains a reserve of germinal cell layers whose proliferation, stratification and differentiation result in production of stratum corneum. The network of elastic fibers in the dermis probably maintains the tonus of the skin, and it is likely that the fibers also provide the small elastic forces which restore the extensibility of slack skin and which allow normal body movements. The horny layer usually contributes the rate-limiting step in the sequence of percutaneous absorption, although the aqueous viable tissues can binder the penetration of very hydrophobic natural or chemical compounds.

With age, the dermal structural fibers change their nature and their organization so that their solubility decreases and various physical properties alter. The skin becomes more rigid, the tensile strenght increases, and the integument wrinkles (1-3).

Furthermore in recently years there has been a growing awareness that many of the so-called attributes of aging skin are, instead, a reflection of environmental assault upon exposed of the body. Of special import are the deterious effects of solar radiation on dermal connective tissue, leading to the visible manifestations of photoaging. The result is a blurred distinction between the characteristics of intrinsic aging and photoaging (4-5).

One of the typical characteristics of aged skin is a partial decrease in the hygroscopic water-soluble components, with a resultant lowered capacity for binding water in the corneum, and hence a dry skin. Moreoever deficiency of the surface lipid is though to be a factor, probably brought about by the lessened contribution of the sebaceous glands in older people, especially in cold weather, and by decreased release of lipids during cornification. Detergents, alternating with water-soaks, may be of particular importance in reducing the elasticity of the keratin. With low relative humidity and cold weather, the stage is set for asteatosis (4).

Stratum Corneum and surface skin lipids

The stratum corneum consists of protein enriched corneocytes embedded in a lipid-enriched intercellular matrix, a continuous lipid phase surrounding a discontinous protein phase. Sebum and sweat flow on the horny layer as heterogeneous mixture of lipids, water and mineral salts, known as the surface lipid film (6).

This mixture enriched with amino-acids, pyrrolidon-carboxylic acid (PCA), sugars and other hygroscopic derivatives from filaggrine catabolism, filters between the corneocytes too from NMF (Natural Moisturizing Factors). NMF is made up of a set of substances acting as skin moisturizers capable of "binding" water from "perspiratio insensibilis" and retaining it (7).

For this purpose, the aim of so-called emollients and moisturizers is not only to act as simple lubrificants, but to maintain skin homeostasis. Well formulated cosmetics delay water evaporation in the "perspiratio insensibilis" , increasing the capacity of the stratum corneum to retain water and restoring the surface lipid film, which is the indispensable regulator of water exchanges (8).

Sebum and Skin Hydration

In Cosmetic Dermatology, moisturizing creams are used to solve the cosmetic problem of dry, dehydrated and aged skin.

These creams are made up of a set of lipids, water and different kind of active compounds.

The water in the emulsion system plays an important role as an emollient, as a vehicle in O/W emulsions, or as the dispersed phase in W/O types. Water delivered by the cosmetic could break the interprotein hydrogen bonds of the keratins and induce a rapid soothing effects.

The selection of lipids and active compounds

together with their physical and chemical features is fundamental for the hydrating capacity of the cosmetic. It is not to be forgotten that lipids, due to their more or less accentuated occlusive power, induce build up of water in the skin vehicle interface and, having an affinity for sebum thus also helping penetration of the moisturizing active compounds. However, the same affinity of both water and lipids is an important factor for their distribution through the skin layers.

Therefore the content in the vehicle of more "porous" and "hydrophilic" unsatured fatty acids, such as linoleic and gamma-linolenic acid is not to be underacted. The topical administration of both linoleic and gamma linolenic acids balances the fluidity and hydrophyly of the cellular membrane, thus helping exchange of hydrosoluble compounds such as NMF and definitely improving hydration of the whole cutaneous ecosystem.

Emollient lipids

It has applied the term emollient to those substances which help to maintain the smooth, soft and pliable texture of the normal skin surface, and in this context it is regarded the cutaneous lipids as naturally occurring emollients (9).

Lipids play two distinct roles in emollients action. One purely physical role of lubrification and protection, and the second in maintaining the correct degree of hydration of the stratum corneum. Emollient preparation usually contain components selected on the basis of compatibility with skin lipids, often trying to simulate the composition of sebum. It is not to be forgotten that skin surface lipids are made up of fatty acids with chain lenghts from C8 to C22, waxes and cholesterol esters with chains between C26 and C42, tryglicerides, squalene and a small amount of paraffins with lengths of C16 to C32, from the external enviroment. Moreoever the 15% of all fatty acids, whether free or not, and of wax-related alcohols are made up of saturated and unsaturated branched chain acids making the surface lipidic film more "porous" and water permeable (10-11).

The presence of saturated and unsaturated fatty acid glycerides in human sebum and in skin surface lipids suggest the use of this type of material as emollients in creams and lotions. This has been achieved by the inclusion of numerous vegetable oils in emulsions, such as peanut, sanflower, olive, borago, avocado, etc..

The major drawback to these emollients is that the polynsaturation render them prone to development of rancidity, which may be retarded by the use of antioxidants. However, there has been an awareness of the essential role played by the polynsaturated fatty acids in skin metabolism and they may be valuable additives for emollient creams. The free fatty acids in human sebum undoubtedly contribute a degree of emollient effect to the skin by virtue of their slip characteristics and mildly occlusive properties. Considerable quantities of stearic and palmitic acid are used in creams, to provide excess fatty acids, to serve as bodying agents, emollients and skin protectants. Another important group of used emollients are the alkyl esters, such as isopropyl myristate and isopropyl palmitate. They are light oily, polar in nature because of an ester group in the molecule. These esters are among the most readily spreading of all emollients when applied to the skin, imparting a smooth, relatively non greasy film.

Their hight solvent power, moreoever, is effective in blending otherwise immiscible oils and waxes, and to plasticize this phase of the emulsion higher melting waxes because the oils impart added slip to the oil-wax phase when applied to the skin.

Natural phospholipids also have been used topically as a moisturizing emollient for many years because of their inherent compatibility with the lipids in the skin. Unfortunately natural phospholipids do not show an high degree of substantivity and their effect, when applied topically, is thus short-lived. Recently it has been

discovered that reversing the placement of the phosphate and cationing grouping in the phospholipid molecule provides phospholipids which interact favorably with the natural lipids in the skin showing a high degree of substantivity and skin affinity (12).
The selective adsorption by keratin or substantivity of emollient lipids to the keratin of the stratum corneum are characteristics that contribute to the total emollient effect. At the end the frictional properties of emollients are another aspect of the complex process of emollient action as they relate to the degree of slip and smoothness.

The Alpha-Hydroxy Acids

Another category of cosmetic compounds known to influence the qualitative character of the stratum corneum are alpha-hydroxy acids (AHAs). AHAs appropriate for cosmetic use include a number of acid compounds that occur naturally in foods: glycolic (sugar cane), citric (citrus fruits), lactic, (sour milk), malic (apples), tartaric (fruits and grape wine) and other of similar distinction (13).
They seems to determine the quality of the stratum corneum at its formation, promoting normal cohesion among the newly formed cells.
The efficacy of the AHAs on dry and aged skin is readily demonstrated in extreme cases where the stratum corneum is visibly thickned. In such cases the return to normal appearance of the skin occurs within a span of few days and remain so for several days following discontinuance of topical applications. It should be emphasized that the alpha-hydroxy acids primarily are not moisturizers, although because of their normalizing effects on stratum corneum formation, they may obviate the need for horny layer but reduce abnormal cell cohesion at the level where the stratum corneum is laid down.
AHAs seem to exert their influence on corneocyte cohesiveness by interference with formation of ionic bonds.
This action seems to be mediated by interference with the functions of enzymes that form O-S and O-P linkages of sulfate and phosphate bonds (14).

Topical tretinoin and photoaging

Topical tretinoin has been shown to improve photoaged skin. When sun is avoid for a number of years, a layer of new collagen slowly appears in the papillary dermis of photoaged human skin.
The same regenerative process has been observed in hailess mice when exposure to UV radiaton is stopped or when sunscreen protection is provided.
Topical tretinoin greatly accelerates the formation of this new subepidermal collagen zone during the postirradiation period.
The newly formed collagen is normal in appearance, both histochemically and ultrastructurally. Fibrobalst are more numerous and more metabolically active, producing increased amounts of dermal matrix components.
Besides stimulating new collagen formation, tretinoin may enhance dermal repair by inhibiting collagenase.
With the promotion of new collagen formation in the papillary dermis, fine delicate wrinkles of photoaging are effaced.
Topical tretinoin also stimulates the formation of new dermal blood vessels.
With increased cutaneous blood flow, photoaged skin has increased turgor and a rosy-pink glow.
Topical tretinoin stimulates increased epidermal cell turnover, resulting in greater epidermal thickness.
Rough, sun-damaged skin becomes smoother and has a more healthy youth full look (15-18).

Identification of the cutaneous biotype

It is difficult to correctly evaluate dehydrated, alipidic, and oily skin. Current efforts to acourately classify skin types are based upon naked-eye and magnifying-glass examinations and palpation. Further obsevation employ simple instruments, such as a spatula, vitropreasure slides, Wood's lamp, ect.

A new technology the 3C SYSTEM Dermotech has changed all this. This computerized system allows a thorough cutaneous check-up. It permits a simple and quick determination of the quantity of lipids at the surface of the skin, a reading of the water content linked to NMFs, and pH of the skin. All of this is done while ambient environmental conditions are automatically standardized.

Measurements of moisture content provide an index for hydration or dehydration. Measurements of lipid content provide a soothing index. These accurate mathematical values are available on a computer screen and can be printed out, as desired (19-20).

This remarkable new technology provides information necessary for the selection of products correctly formulated to rebalance the hydration and surface lipidic film. Differeting skin types classified according to numeric references similar to those now used for sun protection, may be matched to specific cosmetic lines, based upon a factual reading of the patient's cutaneous ecosystem. The printer, which is an integral part of this advanced system, provides a permanent record of whatever data the clinician may require. The stored medical history, prior visit information, and all other previously entered data are available. The patient can be provided with a printed description of the measurements taken at each encounter, as well as the products which are recommended for the continuation of the treatment program.

This precise identy card, the "Skin Beauty card", includes the treatments provided at each visit to the medical office and an outline of all products which the person is supposed to be using at home. The "Skin Beauty Card" may become a part of the individual's permanent clinical record.

Conclusion

Relationships between cosmetic and skin hydration, cosmetic and keratinogenesis, cosmetic and aged skin in general are going to be deepened in the future. Neverthless, if it is true that cosmetic treatments help to improve both the external aspects and function of the skin, they are not in themselves enough for restoring an altered or aged skin. Therefore, it is still necessary to have sufficient sleep and to avoide smoking and excessive alcohol that have been proved to increase skin ageing. Finally, a natural, rich and balanced diet is fundamental to achieve a better quality of life.

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SYSTEM APPROACH TO COSMETIC PRESERVATION BY USING FOOD-GRADE ADDITIVES

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Synopsis

The search for new, effective, non toxic chemicals which can aid in cosmetic preservation is hampered by several restriction.

First, developing a new germicide and getting it approved costs from 1 to 10 million $US.; second, it takes a great deal of time (10 to 12 years) and effort to get the product to market; and third, questions of safety and environmental impact are now key issues.

For a number of years my approach to this problem was to examine chemicals which have been used in the food industry, using them to help create a hostile environment within the composition of cosmetics. data is presented indicating that lipids, antioxidant, and chelating agents have potential for such use as preservatives. Used alone or in combinations, their multi-functional properties make them ideal candidates for cosmetic formulae.

Riassunto

La ricerca di nuovi composti chimici efficaci e non tossici da utilizzarsi quali conservanti per i cosmetici è limitata da molte restrizioni.

Primo, sviluppare un nuovo germicida ed ottenere la approvazione nell'uso costa da 1 a 10 milioni di dollari U.S.A.; secondo, richiede un grande dispendio di tempo per idearlo ed introdurlo sul mercato (da 10 a 12 anni); terzo, la sicurezza nell'uso e l'impatto ambientale rappresentano le nuove chiavi di volta difficili da rispettare.

Per molti anni il mio approccio al problema è stato quello di esaminare le sostanze chimiche di uso alimentare in grado di creare un ambiente ostile ai batteri, se inserite nei prodotti cosmetici. I dati riportati indicano che i lipidi, gli antiossidanti e gli agenti chelanti posseggono tali proprietà, se usati quali preservanti. Date le loro proprietà multifunzionali, questi composti utilizzati da soli o in combinazione, sembrano essere candidati ideali per le formulazioni cosmetiche.

I wish to advocate a very simple concept to inhibit biodegradation of cosmetic products. The principles to be discussed can be applied to other fields. While the concept is not new, emphasis for its application is more timely today than ever before for two very good reasons; a) our deep and abiding concern with mammalian toxicology and environment impact and, b) economics. We are only beginning to appreciate some of the problems involved in product preservation. Rather than have industry spend efforts on developing new chemical preservatives, I strongly feel we need to use present preservatives more imaginatively and to look to the food industry for safer chemicals which could be used to inhibit microorganisms.

What I propose for your consideration is the fashioning of a hostile environment rather than using a preservative as an add-on into product. For our purposes, the term "hostile environment" is the environment of the product that is not conducive for a microorganism's growth or survival. Looking at the product to be preserved from that point of view, it is no longer acceptable for formulators to create a product which is very elegant from an esthetic or functional standpoint, and then turn around and give it to microbiologists and say, "preserve it".

The microbiologist has a limited category of chemicals that he/she can use. The microbiologist is at the end of product creativity which has been carried out in a domino fashion by specific experts without regard to the problem of product preservation. There is some hope, however, since I see within the cosmetic industry at least, some attempts at getting away from this domino approach to formulation. The traditional domino effect starts out with what marketing would like to have, to what the formulator can do, to what the fragranture can put into it, and then finally to the microbiologist. The microbiologist now has to create or make the environment of the product hostile to microbial contamination.

In industries where microorganisms are a problem, the "system approach" will allow us to look at spoilage from a more global point of view and make life easier for all of us concerned with biodegradation. If we share each other's problems, there are many ways this can be done. As an example, the formulator of a cosmetic may choose a surfactant which is antagonistic to the preservative effects; i.e., the use of the ethoxylated surfactant Tween 80. While this surfactant is very good for solubilizing lipophilic chemical, it is a poor surfactant to select since the microbiologists routinely uses Tween 80 to neutralize lipophilic germicides. Now, if the formulator isn't cognizant of the fact, he/she is going to solve their need of solubility esthetics with Tween 80 or some other ethoxylated surfactant and not realize what kind of problem he/she is making for the microbiologist. Thus, the problem of product preservation should be solved by considering the formula as a system. Using this system approach, every chemical in the system (formula) needs to be considered as either adding to the hostility of the system or preventing normal levels of preservative to be effective.

Any single germicide/antiseptic or chemical used to prevent product deterioration by microorganisms has limitations. These limitations can be several: the spectrum of organisms which are effected is small; adverse toxicology and environmental impact; and high cost. The latter is particularly true if we are dealing with a new preservative. The cost estimated in 1989 is $12.5-22.0 million (U.S.) and the time required for commercializing is 10-12 years. The great investment of monies and time precluded the presentation of too many new chemicals to the marketplace.

One solution which I have advocated for a number of years is the use of food-grade chemicals as part of a preservative system (2-4). These substances represent a wide and divergent group of chemicals; i.e., chelating agents, acidulants, antioxidants, and surfactants. While each class of chemical has properties which are lethal to microorganisms, they have low mammalian toxicity. Used in combination, food-grade chemicals have low toxicity and can be formu-

lated to be extremely effective.
Discounting water activity of a system as part of our discussion, the food class of chemicals to be considered are chelating agents, acidulants, antioxidants, and surfactants (emulsifiers).

Chelating Agents

Chelating agents are good examples of a lack of preservative/germicide technology transfer from one field to another. Chelators were first used in the sanitizing field long before they were considered by the cosmetic and food industry as potentiators of preservation activity. Ethylenediamine-tetraacetic acid (EDTA) is one of the best known and widely used chelating agents since 1930. Its most popular use was with quaternary disinfectives. Before the early fifties, quaternary compounds were one of the more popular chemicals used for disinfecting surfaces. They were, however, inactivated by heavy metals. Consequently, sanitizing solutions today contain 1-5.0% of EDTA. It was also observed that even in distilled water "quats" with EDTA were more effective than without the chelator. Obviously EDTA played a role other than a "simple" chelator. The full potentiating effect of EDTA was first reported by Repaske (5) and MacGregor and Ellinger in the late 1950's (6).
The results of these and other works suggested that EDTA exerts an action on the outer wall of microorganisms, particularly Gram-negative bacteria. While EDTA has its greatest effect on Gram-negative strains, it increases the cell wall permeability of many bacteria (7) and hence makes resistance bacteria more sensitive to many different preservatives especially for Gram-negative species (8).
This information, which was available to the people in the sanitizing industry, did not transfer over into the cosmetic area until Roger Hart's report (9). It is only recently that it has attracted attention in the food area as a preservative.

Acidulants

Another variable in the system which can be controlled is the pH. Generally low pH values are hostile to Pseudonomads which are usually resistant to many germicides and antibiotics but are extremely susceptible to vinegar (3% acetic acid). As a rule of thumb, the pH of a product should be as low as possible. Obviously the end use of the product, topical or internal, places limits upon the practical pH that can be considered. It is important to remember that as long as the solution/product is not buffered, large swings in values (pH 2.0-8.5) can be tolerated by biological systems other than microorganisms.
Two acidulants which are extremely useful are citric and lactic acid. The reason I prefer these two acids is that they have multi-functions in the formula and are food-grade chemicals. Citric can function as an acidulant, chelator and provide a taste characteristic in a product; Lactic acid, besides functioning as an acidulant and chelator, is looked upon as a moisturizing agent in skin products (10).

Antioxidants

While antioxidants are generally not commonly found in cosmetic formulations, you do find them in lipsticks and in other products that have natural oils or unsaturated fatty acids. The unsaturated fat or lipid is protected from oxidizing and breaking the emulsion or also giving off on odour. These antioxidants have a very interesting chemical structure which is probably not often appreciated. They are phenols.
Two antioxidants commonly used in the food industry are butylhydroxy toluene (BTH) and butylhydroxy anisole (BHA). Although the accepted use of these antioxidants is to prevent rancidity in food products (14), their antimicrobial character needs to be exploited as part of a systems approach to biodegradation. The minimum inhibitory concentration of the two food-grade phenolics was compared with a popular cosmetic preservative [Table 2 (3)]. While both BHA and BHT are very good antioxidants, BHA seems to be superior as an antimicrobial agent. In preparations where you are dealing with an antioxidant, all things being

Table I.

Preservatives Known to be Enhanced by EDTA (R. Hart, Ref. 9)

Cationic preservatives
- Quaternary ammonium salts
- Benzalkonium chloride
- Benzethonium chloride
- Myristalkonium chloride
- Cetylpyridinium chloride
- Cetrimonium bromide
- Lauryl pyridinium chloride
- Lauryl isoquinolinium bromide

Other cationic compounds
- Quaternium 15
- Chlorhexidine digluconate
- Chlorhexidine dihydrochloride

Anionic preservatives
- Parabens
- Methylparaben
- Propylparaben
- Butylparaben
- Ethylparaben
- Benzylparaben
- Sodium methyl paraben

Other phenolic compounds
- tert-Butyl hydroxyanisole
- Di-tert-butyl methylparaben
- Triclosan
- Chloroxylenol
- Sodium o-phenyl phenate
- Salicylic acid
- Resorcinol
- Phenol

Miscellaneous anionic preservatives
- Sorbic acid
- Potassium sorbate

Nonionic preservative
- Imidazolidinyl urea
- 2-Bromo-2-notropropane-1,3-diol
- DMDM hydantoin
- Phenethyl alcohol
- Monolaurin (Lauricidin®)

equal, I would recommend BHA over BHT for that reason. Other antioxidants (tertiary butylhydroquinone, TBHQ; propyl gallate) have been used. The reader is referred to reviews and references of these reports (15-17).

In his studies on the potentiation effects of certain antioxidants as preservatives, McCarty et al. (18) showed that propyl gallate was particularly useful due to potentiating effects of other preservatives. The Minimal Inhibitory Concentration (MIC) of BHA against S. aureus (125 ppm) is much lower than the MIC of methyl (4000 ppm) or propyl (500 ppm) parahydroxy benzoate. (See 18 and references therein.) Activity against Ps. aeruginosa and E. coli was reported to be 1000 ppm and 250 ppm, respectively (19).

Surfactants

Before 1930 it was felt that chemicals, except for phenols and toxic metals, could never be expected to control growth of bacteria. However, the early recognition that certain surfactants were germicidal stimulated study of this chemical group. For early reviews, the reader is referred to Glassman (20) and Schwartz et al. (21). Surfactants, therefore, represent a large pool of potential hostile substances. because most surface-active agents (except nonionics) are antimicrobial, this category offers a large and diverse group of chemicals to the formulator. A classical example is sodium lauryl sulfate or sodium lauryl sarcosinate. The two surfactants are so active that soap products made with either of these surfactants need little or no preservatives to protect them from biodegradation.

The surface active properties of an aliphatic surfactants parallel their germicidal activity. That the two properties are parallel but not related can be deduced from testing nonionic surfactants. The latter surfactants are not active against microorganisms except for a few exceptions.

The antimicrobial property of an aliphatic surfactant is dependent on chain length. This relationship, which becomes optimal at a specific carbon length, depends upon the polar or non-polar part of the carbon chain and the organisms under test. There appears to be little overall differences in bactericidal effects which can be ascribed to branching of the chain (21).

With a given chain length, the position of the hydrophilic group(s) is an important variable in determining surface properties and biological activity. The kind, geometric isomer and position of unsaturation can influence biological activity. In general, the acetylenic containing fatty

Table II

The MIC of BHT and BHA (μg/ml) (pH 7.0) In Liquid Culture Medium Compared to Propyl Parabens

Microorganisms	BHT	BHA	Parabens
Escherichia coli	>5000	2000	625
Pseudomonas aeruginosa	>5000	>5000	>5000
Streptococcus mutans	>5000	125	625
Streptococcus agalactiae	>5000	125	625
Staphylococcus aureus	>5000	250	313
Corynebacterium sp.	500	125	—
Norcardia asteroides	>5000	250	—
Saccharomyces cerevisiae	>5000	125	313
Candida albicans	>5000	250	1250

acids are more active than the ethylenic members. In the ethylenic series, the cis form is more effective against microorganisms than the trans form (22).

As a group, surfactants are categorized into three groups: a) cationic; b) anionic; and c) nonionic. The most popular group is the cationic group which is represented by quaternary compounds. While these surfactants enjoy a great deal of commercial success, it is well to remember that they also represent the most toxic and most irritating surfactants (Table 3, following).

The anionic surfactants are frequently active only against Gram (+) and yeast organisms and are rarely effective against Gram (-) strains. Their action is less rapid than the cationics and is more susceptible to changes in the pH of the system. The nonionic surfactants are not generally considered to be germicidal. However our own research with monoesters of fatty acids had indicated otherwise. Suffice to say that esters of polyhydric alcohols, amides and aminimides are nonionic surfactants but still have good germicidal properties.

Because nonionic surfactants are generally less toxic, less irritating, I was intrigues by our finding a nonionic lipid with antimicrobial activity (2,3,4). The interesting properties of this lipid (monolaurin) is what lead me into the field of preservation. The story will help the audience better understand my philosophy of how best to stop biodegradation ion a product and to use safe (nontoxic) chemicals. (Note monolaurin in my discussion refers to the distilled monoglyceride (Lauricidin®) 95% monoester content and not to commercial glycerin monolaurate, 45-55 monoester content.

The Problem - The Solution

Basically, the problem in preventing deterioration of a product is to kill the organism or to lower or prevent end-products of metabolism which can cause spoilage. In the first case, organisms can be killed by a lethal chemical or the organisms can be prevented from adhering to the surface. In either case, the organisms is "removed" from the surface. Adherence, while an important part of surface spoilage or contamination and needs to be considered in depth, will not be further pursued in the limited time available for discussion. The other factor (metabolic end-products) involved in spoilage becomes of academic interest since in most studies quality control depends on creating an environment which is lethal to the challenge organisms. The problem then reduces itself to understanding the interaction between organisms and chemical. Since this interaction first takes place at the periphery of the cell, it is of some importance to recognize the three different surfaces which a chemical may be presented to interact. These surfaces are represented by Gram-positive, Gram-negative and fungal or-

Table III

Oral toxicity of Some Surfactants

Class of Surfactants	Lethal Dose-50
Cationic	50-500 mg/kg
Anionic	2-8 g/Kg
Nonionic	
Amides/Aminimides	1-3 g/kg
Esters of fatty acids	5-50 g/kg

ganisms. Details of this discussion can be found in a recent book (23).

Simple Gram-negative and Gram-positive strains have similar membrane structure except for a lipopolysaccharide layer (LPL) found in Gram-negative organisms. This LPL causes Gram-negative bacteria to be more resistant to chemical effects than Gram-positive bacteria. fortunately Gram-negative organisms can be made susceptible to chemical agents by their initial/simultaneous exposure to chelating agents. Chelating agents (EDTA, lactic or citric acid, etc.) help remove the lipopolysaccharide outer layer of the Gram-negative bacteria. With this layer removed, Gram-negative strains are as or more susceptible to chemicals as compared to Gram-positive strains.

The third class of microorganisms are yeasts and fungi. While they have an entirely different surface from the first two, I have found that with simple molecules (fatty acids and their corresponding polyhydric esters) short (C8-C11) chains are more effective than longer chains (C12-C18); also phenolic type compounds tend to effect these organisms.

With the above as a guide, we decided that a combination of three types of chemicals would provide wide spectrum anti-microbial activity to any product (24). To this end, I combined monolaurin, parabens and chelating agent to help create a nontoxic hostile environment in which microorganisms could grow or even survive. A simple example will suffice. An oil-water emulsion (Inolex 7134C) and a water-oil emulsion (Inolex 7149A) were used as model systems. They were challenged with 106 CFU/ml of P. aeruginosa. Samples were taken at 24 hours, 48 hours, and one-week intervals and examined for colony counts. Data for the water-oil emulsion is presented in Figure 1 (24).

The data indicates that the preservative mixture at 0.7% or more reduced colony counts to less than 30 CFU in 24 hours; by 48 hours the 0.3% showed a reduction of about 50% in CFU/ml; and after one week the level or organisms even in the lowest preservative concentrations for the mixture was below limits for detection. Control levels during this type were at or greater than original inoculum.

As suspected, oil-water emulsions were more

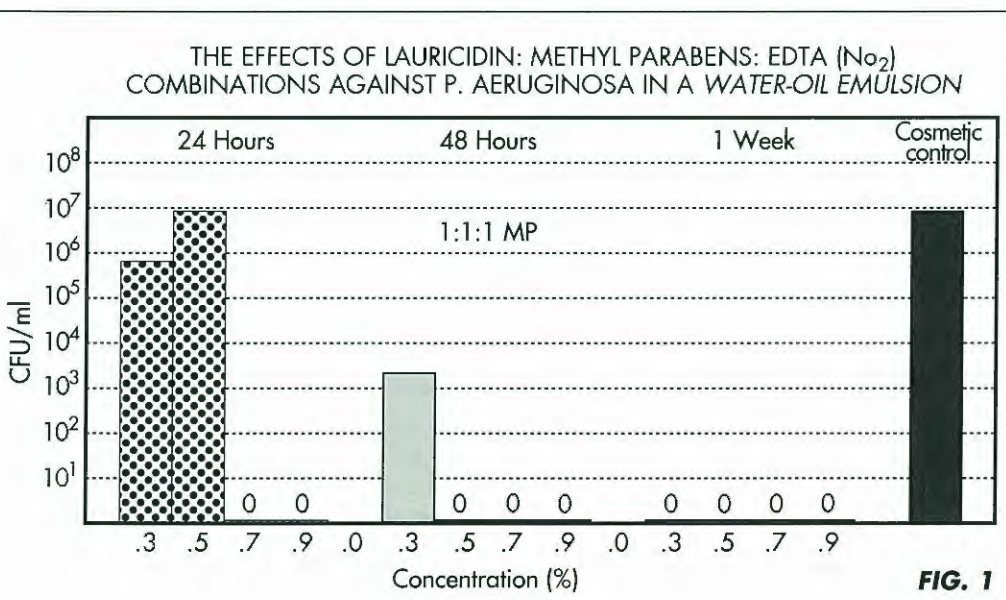

FIG. 1

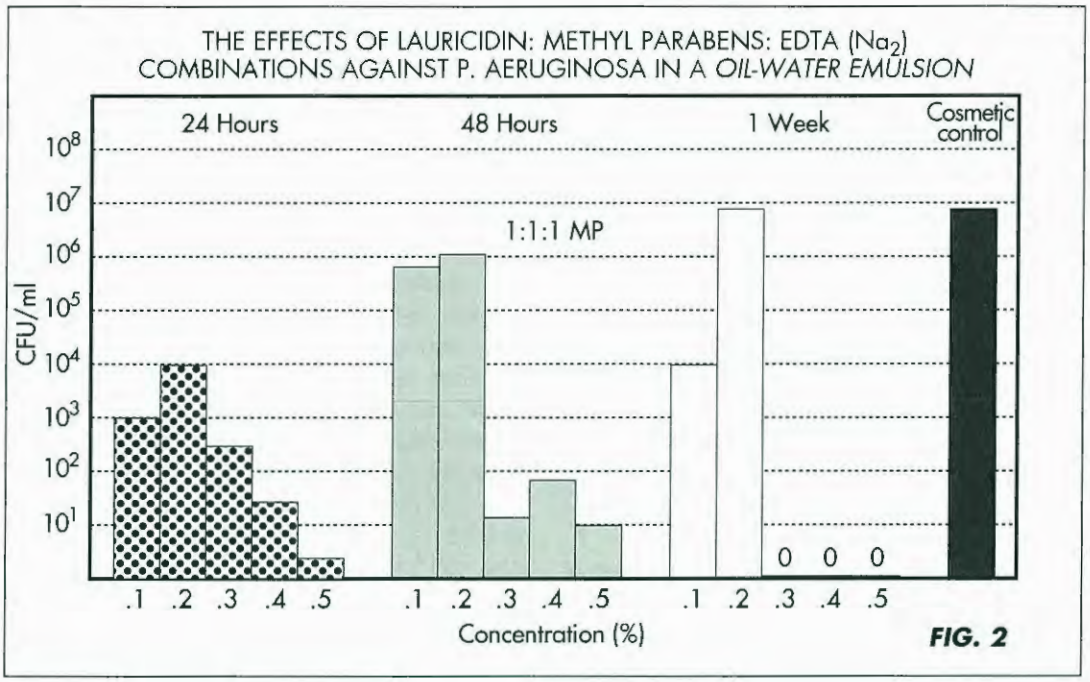

FIG. 2

difficult to preserve (Figure 2)

Using the same organisms, samples with 0.3% or greater showed loss of organism after 24 hours; at 48 hours, levels of organisms were significantly reduced. At preservative concentrations of 0.3% or greater, there were no detectable organisms (24). That the combination of monolaurin (Lauricidin®), and chelating agents alone were sufficient for a good preservative system is shown by the following data (Table 4). High levels (0.3%) of EDTA alone were effective towards P. aeruginosa. Combinations of both levels of 0.2% were effective.

Also, under similar conditions, trials with propyl parabens proved to be less effective when compared to the methyl derivative.

Thus, in most cases the monoglyceride (Lauricidin®): and EDTA (1:1) is effective at concentrations as low as 0.3%. Not only is this combination safe, but this and other system approaches may be of an economic advantage. This is particularly true where the monoglycerids acts as a multi-functional; i.e., emulsifier, emollient, preservative.

The bottom line of my discussion is very simple. Food-grade chemicals (methyl parabens, BHA, EDTA, and monolaurin) are both safe and effective chemicals on which to build a preservative system. By using chemicals which have a long history in the food area, we can feel that toxicity of our preservative systems will not be a problem for the future.

I'm sure I have only scratched the surface of food-grade/natural compounds which could help us solve issues of environmental safety without becoming part of the problem in terms of chemical toxicity. The challenge is for the next generation to find and use chemicals in a safe manner.

Killing microorganisms isn't the solution to the preservative problem. Killing them without effecting man and our environment is a desired goal. Preservative-free cosmetics is a reachable ideal. Further details can be found in a recent 1991 publication (25).

Table IV

Preservative Effect of Food Grade Chemicals in a Lauricidin Lotion Oil-Water System [a] (24)

Preservative	At 24 hrs		At 48 hrs		At 1 week	
	Pseudomonas aeruginosa	Escherichia coli	Pseudomonas aeruginosa	Escherichia coli	Pseudomonas aeruginosa	Escherichia coli
EDTA						
0.1%	+	+	+	+	—	—
0.2%	—	±	—	±	—	—
0.3%	—	±	—	±	—	—
Methylparaben						
0.1%	+	+	+	+	+	+
0.2%	+	+	+	+	+	+
0.3%	+	+	+	+	+	+
EDTA + methylparaben						
0.1% + 0.1%	+	+	+	+	—	—
0.2% + 0.2%	—	+	—	+	—	—
0.3% + 0.3%	—	±	—	+	—	—

a. +, growth; ±, slight growth; —, no growth.

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SKIN HYDRATION AND LIPID CASUAL LEVEL: A QUANTITATIVE MONITORING IN ITALY

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Key word: *Skin Hydration; Skin Lipids, 3C System®; Horny Layer; Skin Dehydration; Italian Skin Monitoring.*

Synopsis

The plasticity of the horny layer, and thus of the skin itself depends on a minimum content of 10% water. In addition, the surface lipids and sebum (Casual Level) are known to play a major role in controlling the skin's water balance. Both hydration and skin lipids, however, differ between different skin areas in respect of their pharmacology and their modifications arising from environmental causes. This work was designed to compile basic data on skin hydration and surface lipid for a broad population. The subjects were 3673 people of different ages and from different climatic areas. For monitoring the data the new 3C SYSTEM computerized equipment was used for its rapidity of use.

Riassunto

La plasticità dello stato corneo e della stessa pelle dipendono dalla presenza di un minimo contenuto di acqua di circa il 10% . Inoltre giocano un ruolo fondamentale sia la presenza del film lipidico di superficie che i lipidi intercellulari, che regolano il bilancio idrico cutaneo. Infine sia l'idratazione che i lipidi cutanei variano nelle diverse aree cutanee e la loro presenza è condizionata dall'umidità relativa dell'ambiente e dall'assunzione di farmaci.
Con questo studio si è voluto effettuare un primo controllo dell'idratazione e del mantello lipidico cutaneo di superficie di un panel significativo della popolazione femminile italiana. Infatti sono state effettuate misurazioni su 3673 persone rappresentanti diverse fasce di età e provenienti da differenti zone climatiche. Le misurazioni sono state eseguite con un nuovo apparecchio computerizzato, il 3C System ® che permette rilevazioni molto rapide e precise.

The plasticity of the horny layer and thus of the skin is known to depend on a minimum amount of water at cell level (1-3).
This water amount plays a major role in maintaining the balance of the skin ecosystem, and is controlled by both the surface lipid film and relative humidity in the outside environment (4-6).
As a matter of fact, skin hydration varies considerably with the change of seasons and is highly affected also by the environment (7).
It increases in the summer, when relative humidity is very high, and decreases in the winter.
Changes in skin hydration are tightly linked to the relative humidity in the environment. As a result, they are highly affected by the climatic characteristics of specific areas. Since the Italian territory stretches over about-2,000 km, including European mountainous continental areas, as well as plains which are quite near to the African continent and surrounded by the sea, surface sebum and skin hydration were measured in a large group of women aged 10 to 60 years.

MATERIALS AND METHODS

Materials (by groups)

A study group including 3,673 female volunteers was divided into 5 sub-groups, as follows:

1) < 16 ys
2) 16 to 25 ys
3) 26 to 35 ys
4) 36 to 45 ys
5) 46 to 60 ys

Sub-groups accounted for the following share of total subjects:

1) 0.9 %
2) 23 %
3) 30 %
4) 22.2 %
5) 23.3 %

As shown also in Fig.1, group 1 was not highly representative due to the difficulty in recruiting volunteers under 15. Group 3 was the largest one (30%); while the remaining groups accounted for almost the same share (22% to 23% approx.).
Depending on climatic areas, the study group was distributed as follows:

NORTHERN ITALY:	1,180	32,2%
CENTRAL ITALY:	1,151	31,3%
SOUTHERN ITALY:	1,342	36,5%

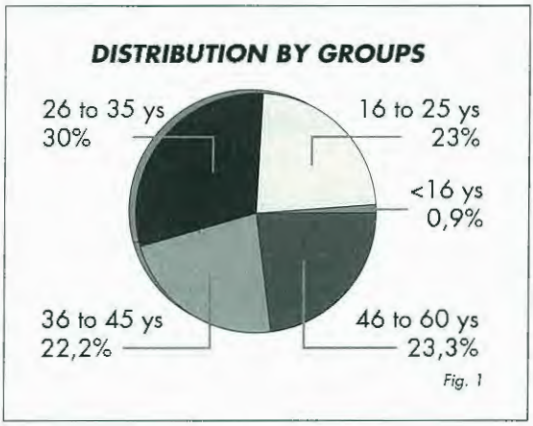

Fig. 1

Methods

RESULTS AND NOTES
As regards the whole study group, that is at national level, the results for surface lipids were as follows (Fig.2):

38.5 % normolipidic
39.3 % alipidic
22 % hyperlipidic

The results for skin hydration were as follows (Fig.3):

22 % normohydrated
75 % dehydrated
2.6 % hyperhydrated

According to climatic areas, results were as follows:

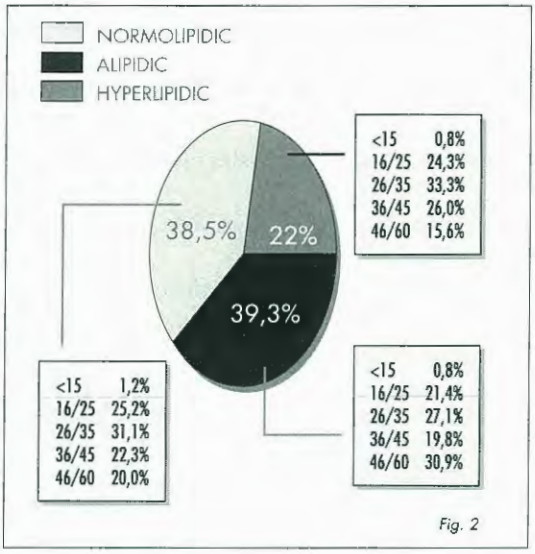

Fig. 2

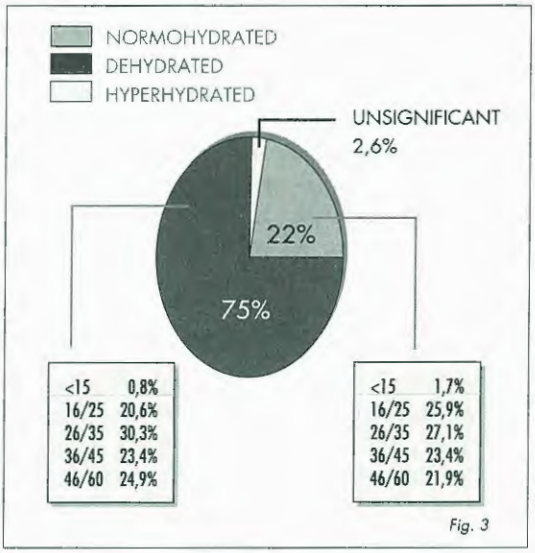

Fig. 3

NORTHERN ITALY:

37%	normolipidic	18 %	normohydrated
48%	alipidic	80.9 %	dehydrated
15%	hyperlipidic	1.1 %	hyperhydrated

CENTRAL ITALY:

36%	normolipidic	21.5 %	normohydrated
45%	alipidic	77 %	dehydrated
19%	hyperlipidic	1.5 %	hyperhydrated

SOUTHERN ITALY:

43%	normolipidic	24 %	normohydrated
27%	alipidic	73 %	dehydrated
30%	hyperlipidic	3 %	hyperhydrated

First of all, data shows that, on average, skin surface lipids in the population of SOUTHERN ITALY are 16% higher than in NORTHERN ITALY, while its hydration rate is about 33% higher if considering the rates for normolipidic and normohydrated skin.

This result is far more interesting if taking into account that volunteers from Sicily, which is an island and, as such, is surrounded by the sea, accounted for 50% of the data for the SOUTHERN ITALY group.

This suggest that the environment of seaside areas, which are probably less polluted and surely more ventilated, helps maintain the surface lipid film and skin hydration.

As regards northern areas, with a higher industrialization rate and larger urban centres, their increased environmental pollution seems to cause a gradual reduction in the surface lipid film and, as a result, skin dehydration.

This first experimental data confirms the well-known large impact of the environment on skin conditions. The high pollution level in big cities, due to both factories and the overcrowding of cars, clearly affects also the skin. Since no such survey has been so far carried out in Italy, it would be necessary to monitor population groups of proper size in order to compare skin values in large and small urban centres, both in seaside and mountain areas, and to determine environmental influences on the skin bioecologic balance.

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KERATOTAL

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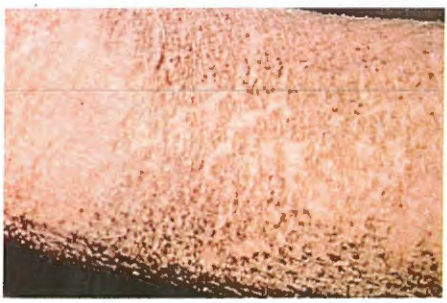
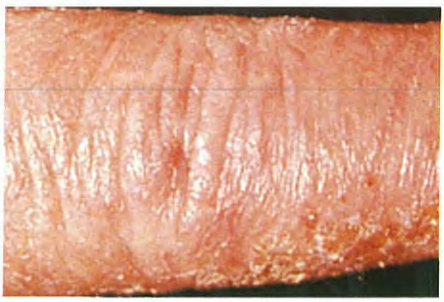


Ipercheratosi intrinseca



Ipercheratosi estrinseca

INDICAZIONI:

Placche da ipercheratosi sia intrinseca che estrinseca, corticoterapia, invecchiamento e fotoinvecchiamento, fragilità cutanee post Radio e/o PUVA terapia, acne, peeling chimici.

KERATOTAL 1
Emulsione - Ammonio Lattato 14%
KERATOTAL 2
Emulsione - Ammonio Lattato 8%
KERATOTAL SHAMPOO
Ammonio Lattato 7%
KERATOTAL BAGNO
Olii lineari e ramificati - Ammonio Lattato 5%

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