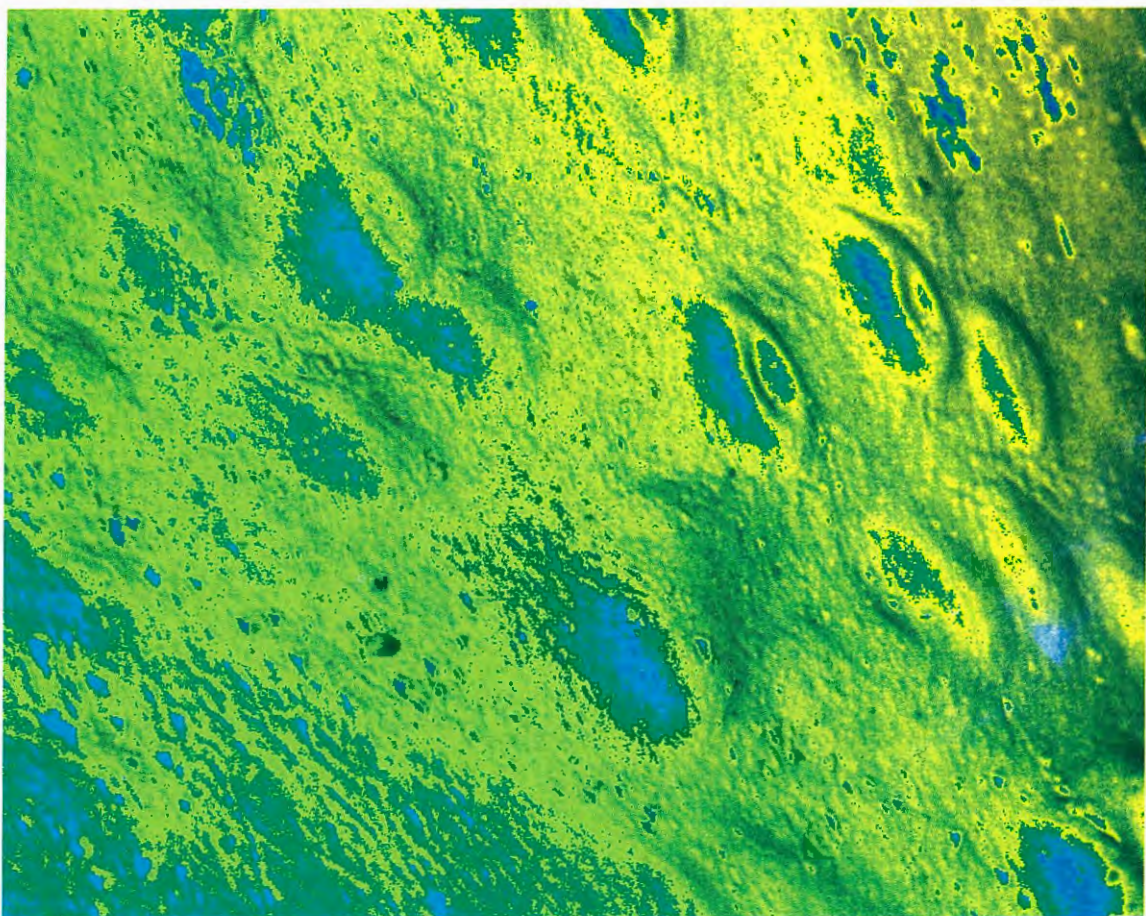


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2
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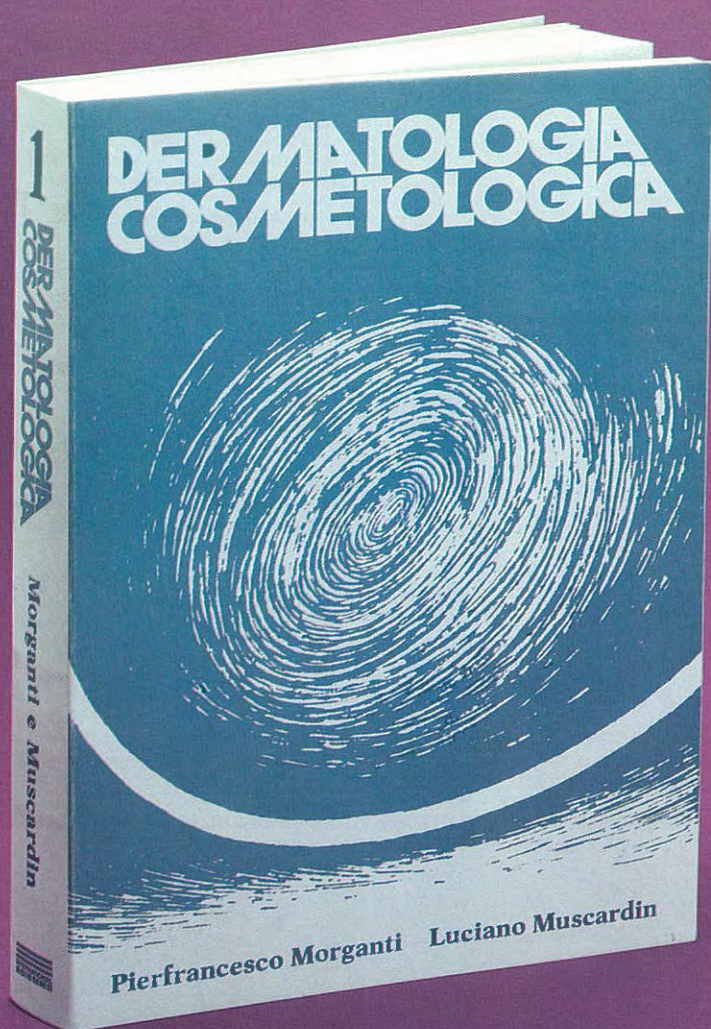
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DERMATOLOGIA COSMETOLOGICA

A cura di P. Morganti e L. Muscardin
Ed. International Ediemme

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1st International Meeting on Cosmetic Dermatology,
Rome, Italy, March 7-9, 1985

Editors: P. Morganti, W. Montagna



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Trimestrale di Dermatologia Cosmetologica

Quarterly Review of Cosmetic Dermatology

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4th International Meeting of International Society of Cosmetic Dermatology
"Progress in Cosmetic Dermatology: Science and Safety"
Rome - Italy October 30-November 2, 1991
Preliminary Program

18° World Congress of Dermatology
New York City - from June 12-18, 1992

TOLERANCE OF THE LESIONED SKIN TO DERMATOLOGICAL FORMULATIONS

B. Gabard*, Th. Nook and K.H. Müller

*Department of Biopharmacy, Spirig AG, CH-4622 Egerkingen (Switzerland)

Received: October 26, 1989; Presented at 3rd International Congress on Cosmetic Dermatology "Progress in Cosmetic Dermatology" - 27 - 29th October 1989, Wien

Key words: Irritation; Scarification; Stripping; Na-Lauryl Sulfate; Propylene Glycol; Urea; Osmolarity; pH; Antimicrobials.

Synopsis

Dermatological formulations often are applied on lesioned skin in the course of the treatment of for example dry skin, eczema or atopic disease. Therefore we felt it important to devise a test for quantification of the tolerance of these formulations. For this purpose, the horny layer was tape-stripped until the transepidermal water loss (TEWL, as measured under standard conditions) attained 40-50 g/cm²h. This needed approximately 10-15 strips. After an interval of at least 30 min during which the TEWL decreased to values of 30-40 g/cm²h, the test products were applied to the stripped area and the reactions were assessed by the volunteer according to a 4-point scale during and immediately after the applications. Standards were used for quantification, identification and comparison purposes: NaCl (0.1-10%), Urea (0.5-20%) and Propylene Glycol (1-70%). In addition the pH of the test solution was varied between 3 and 8. Curves relating-effect to concentration allowed more precise assessment of the relative roles of the different components of formulations. For example, Urea and Propylene Glycol may lead to burning reactions on lesioned skin at the concentrations usually found in dermatological products. Similarly, antimicrobials in permitted concentrations may play a role in these reactions.

Riassunto

Le formulazioni dermatologiche vengono spesso applicate su cute lesa per eccessiva secchezza, per la presenza di eczemi o di dermatiti atopiche.

È perciò importante che venga accuratamente valutata la tolleranza di queste formulazioni. A questo scopo sono stati eliminati mediante "strappo" alcuni strati del corneo fino ad ottenere una TEWL di 40-50 g/cm² h. A tal riguardo sono necessari circa 10/15 "strappi".

Dopo circa 30 minuti durante i quali i valori TEWL raggiungevano il valore di 30-40 g/cm²h venivano applicati i prodotti da sperimentare sulle zone impoverite di corneo.

Rilevando la reattività ottenuta mediante una scala di valori numerici prima e dopo l'applicazione dei prodotti è stato possibile controllare il grado di tolleranza di alcune materie prime di uso corrente, quali ad esempio l'Urea ed il glicol propilenico.

È stata verificata anche l'influenza svolta dal pH, e dalle diverse concentrazioni d'uso permesse.

Professor Albert Kligman wrote in 1982 (1): "In our age of skin consciousness and abundant use of cosmetics and toiletries awareness is growing that the great majority of undesired reactions represent irritancy." And further: "The biologic truth is that all substances are irritating for some persons under some conditions, although extreme exposures may be necessary to bring this to light." End of citation.

The problem of irritation is far from a theoretical one. Irritation could be tentatively defined as a very general notion for undesired reactions. These can widely vary in their intensity, in their manifestations and in the moment they will be perceived as such because people differ enormously in their susceptibility to irritating substances and because the reactivity of the skin is influenced by many factors. In addition, topical preparations, whether drugs or cosmetics, are often applied to damaged skin. Indeed, it is surprising how often creams or ointments are used as home remedies for burns, abrasions, bites, and rashes of all kinds.

Hence it is not out of order or unrealistic to assess the probability of a substance being irritative under the most extreme conditions. This permits discrimination among the test products because reactions are sufficiently intense also

allowing some standardisation. For this purpose, we must make sure that the substance reach the viable tissue under the horny layer. The barrier can be eliminated by scarification, as in the scarification test of Frosch and Kligman (2) or by tape stripping. Testing products on damaged skin is also necessary if, as in our case, are primarily aimed at ill people.

Among the many reactions of the skin which could be classified under irritation we were especially interested in those called "invisible reactions" by Professor Kligman (1). Topical preparations can cause disagreeable sensations - burning, itching, stinging - immediately after application and will be rejected by the consumers, especially in pediatrics. These preparations are not irritative in the ordinary sense and usually do not damage the skin. The reactions can be very intense and unpleasant, and this is why we feel it important, for the products we are selling, to try to evaluate such immediate reactions.

For all these reasons, we performed the tests on stripped skin and recorded immediate reactions. We used the following method (Fig. 1): On the ventral side of forearms, up to 5 areas of approximately 1x2 cm were stripped. Stripping was continued until the transepidermal water

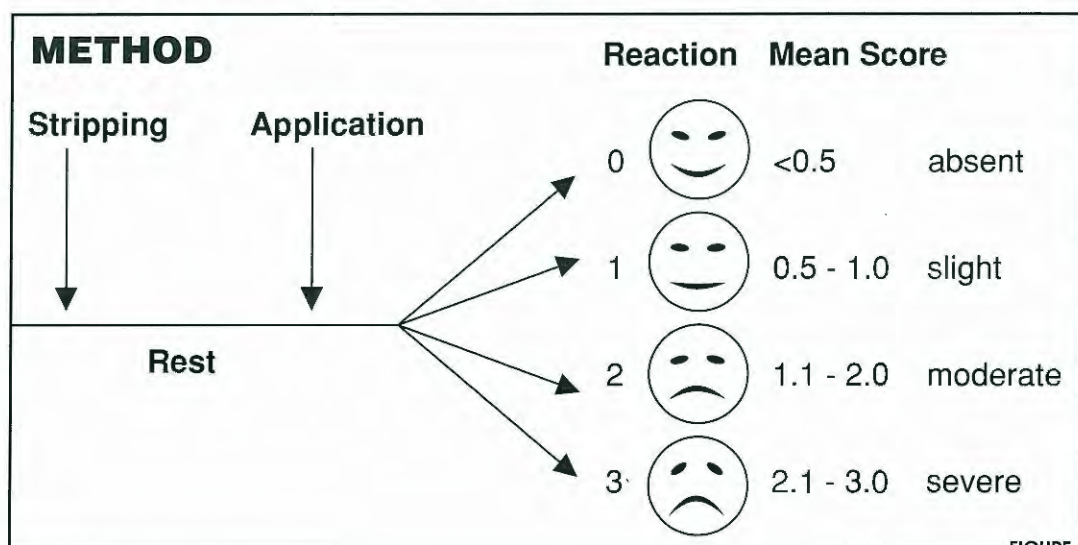


FIGURE 1

loss attained 40-50 g/m²·h which usually needed 10 to 15 strips. Thereafter, a resting period of at least 30 min was observed, during which the transepidermal water loss stabilised around values of 30-40 g/m²·h and the sensation of irritation due to the stripping vanished. The test products were applied on the stripped area taking care to avoid or minimise any mechanical stimulation. Liquid products were dropped on the skin with a pneumatic pipette, creams and ointments were carefully pasted on the stripped surface. The test products remained on the stripped area for a maximum of 3 min. Immediate sensations, mainly burning, were graded on a four point scale from 0 (no reaction), 1 (slight), 2 (moderate) to 3 (severe). Mean scores were calculated and the results expressed as < (lower) 0.4 (no reaction), 0.5 to 1.0 (slight), 1.1 to 2.0 (moderate) and 2.1 to 3.0 (severe). This gradation has also been used by Frosch and Kligman to classify the irritation measured with the scarification test thus enabling comparisons to be made, although we are aware that the two phenomena are completely different in their nature.

First, we investigated reactions to different classes of substances used in topical formulations such as surfactants, penetration enhancers, moisturizers, all in aqueous solutions. Sodium Lauryl Sulfate (Fig. 2) is a good example to show the difference we found between the scarification test and our test. This agent is

known to irritate the normal skin at the concentrations we used and scarification greatly reduces the irritation threshold. Immediate reactions were almost absent up to the concentration of 1%. On the contrary, Propylene Glycol (Fig. 3), which is incorporated in many topical formulations as a penetration enhancer, readily provoked burning sensations when applied on stripped skin but showed a low irritation potential in the scarification test.

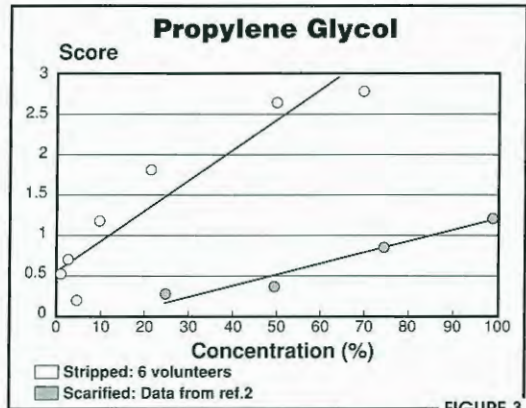


FIGURE 3

Urea (Fig. 4), as a moisturizer, led to a measurable rate of immediate reactions without great dependency on the concentration. Interestingly, higher concentrations did not much enhance this rate, which was almost comparable to the results obtained after scarification.

Among other factors which could have a major impact on the rate of immediate reactions of

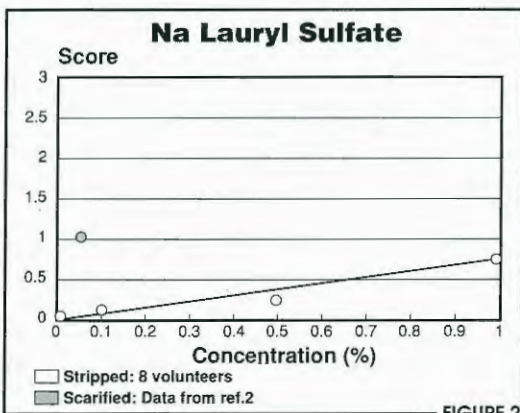


FIGURE 2

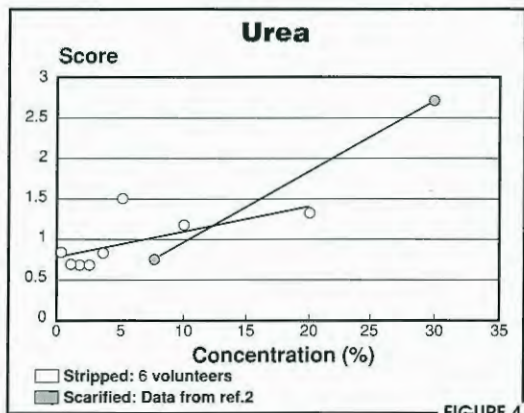


FIGURE 4

stripped skin are the osmolality and the pH of topical formulations. Osmolarity (Fig. 5) was

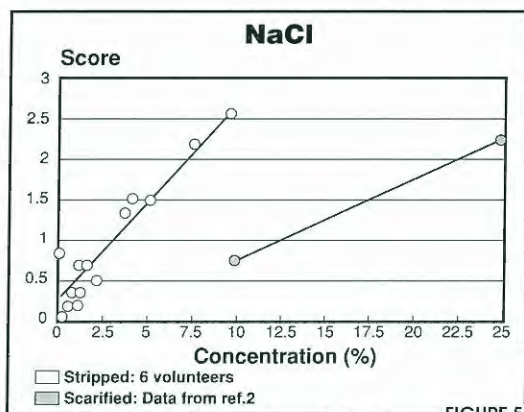


FIGURE 5

investigated with different concentrations of sodium chloride. An interesting finding was a measurable reaction score for distilled water, perhaps due to excessive hypoosmolality. The score always diminished if a low concentration

of sodium chloride was present. The dependency on osmolality was steep, again showing a

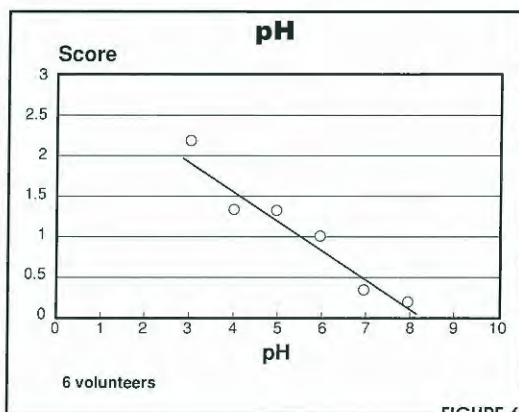


FIGURE 6

marked difference with the scarification test. Isotonic buffers of different pHs (Fig. 6) between 3 and 8 markedly influenced the score of the reactions. Most intensive responses were recorded with a pH under 4.

Table I

Antimicrobial	Concentration %	Score	Vehicle
Triclosan	0.3	0.4	O/W cream
Chlorhexidine dihydrochloride	0.3	0.5	O/Wcream
	0.3	0.8	O/W Lotio / Urea 2%
Hexamidine isethionate	0.5	0	O/Wcream
Phenylethylalcohol	0.5	0.5	O/Wcream
Phenoxyethylalcohol	2.0	2.8	O/Wcream
Triclosan + Chlorhexidine	0.3	0.2	O/W cream
	0.3	0.6	W/O cream
	0.3	0.6	W/O cream
	0.3	0.6	W/O cream
Triclosan + Phenoxyethylalcohol	0.3	1.0	W/O Lotio / Urea 2%
	0.5	1.0	W/O Lotio / Urea 2%
	0.3	2.3	W/O Lotio / Urea 2%
	1.0	2.3	W/O Lotio / Urea 2%

At this stage of the experiments, one could tentatively summarize that for our purposes, a topical product should show a neutral pH and a low osmolarity. Penetration enhancers and moisturizers should not be present or their use should be carefully considered.

It is known that other important factors which often lead to disagreeable reactions are antimicrobial agents. Some relevant data are shown in Table 1. Interestingly, we did not find high reaction scores for antimicrobials incorporated into suitable vehicles in permitted concentrations except for Phenoxyethylalcohol. Addition of urea slightly enhanced the scores as anticipated. Combination of two antimicrobials did not generally lead to higher scores, again with the exception of Phenoxyethylalcohol.

Last but not least, although we feel that immediate reactions are very important for the success of a product, the long-term irritative potential should not be neglected. As pointed out in this communication, the test on stripped skin and the scarification test lead mostly give different results and are not predictive of each other. This was confirmed with a syndet (Table 2). That is, we do not replace the evaluation of a possible irritation as performed with the scarification test by scoring immediate reactions after application of the product on stripped skin. Rather, we consider both tests as independent but useful complements integrated in a product development scheme as an optimization of dermatological formulations before going on the market.

Table II	
Washsyndet	
Antimicrobials:	Triclosan 1,0 % Bronidox 0,2 %
Test	Score
Stripped	1.4
Scarified	2.3
5 volunteers	

Acknowledgement

Thanks are due to E. Bieli for her skilful technical assistance.

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CONTACT ALLERGIC DERMATITIS: THE NEED FOR CONSISTENCY IN DATA COLLECTION AND ANALYSIS

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Received: October 26, 1989; Presented at at 3rd International Congress on Cosmetic Dermatology "Progress in Cosmetic Dermatology" - 27 - 29th October 1989, Wien

Key Words: *Prevalence rate; Relevance; Inter-clinic; Variation; Patch testing; Contact allergy; Dermatitis.*

Synopsis

The alarm that clinical skin allergy reports generate is in some cases greater than that generated by reports of carcinogenicity e.g. cigarette smoking. It would be necessary for the medical community to educate the lay public that the reported prevalence rates are clinical and therefore of not direct relevance to the general population.

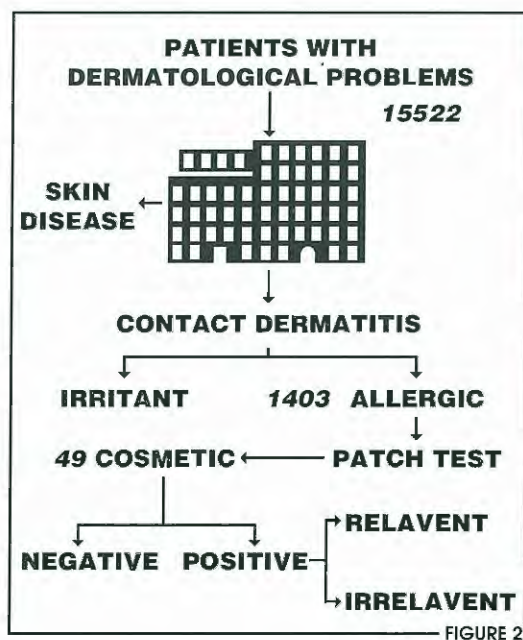
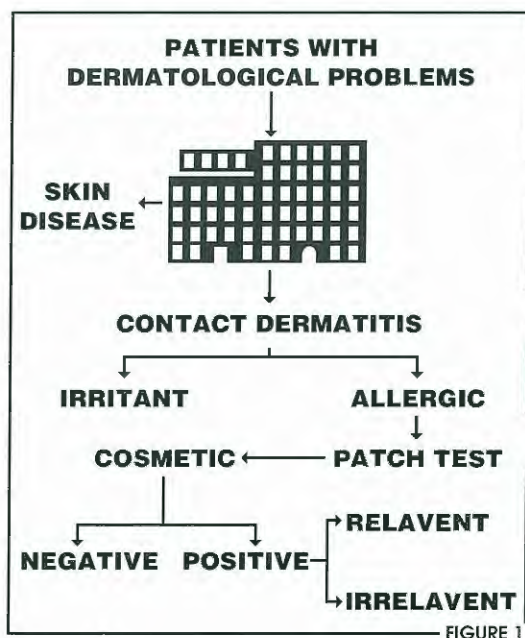
It would be also of paramount importance to educate the public to realise that a positive patch-test is not, of itself, proof that the current clinical conditions was caused by that allergen.

Riassunto

L'attenzione che il grande pubblico riserva agli articoli riguardanti le allergie cutanee è spesso superiore dell'analoga attenzione rivolta ai rapporti sulla carcinogenesi provocata dall'uso delle sigarette. Sarebbe auspicabile, quindi che la classe medica educasse il pubblico a valutare più attentamente i dati clinici perché non sempre l'allergene evidenziato è il vero responsabile di un dato quadro clinico e non sempre la specifica reattività cutanea di pochi individui è estensibile ad una vasta popolazione.

There is currently a heightened awareness, on the part of the general public, of the problems associated with skin allergy, contact allergic dermatitis. This awareness, particularly in the area of cosmetics and toiletries, is in some respects a consequence of our consumer conscious society and is fuelled, at least in part, by reports in the popular media derived from clinical data. Data are published by the practitioner in medical Journals such as the Lancet and Contact Dermatitis, and these are now common hunting grounds for scientific journalists. The concern and alarm that these allergy reports generate, can in some cases be greater than that generated by reports of carcinogenicity e.g. cigarette smoking. I believe that, given this climate, it would be timely for the medical community to educate the lay public to realise that the reported prevalence rates are clinical data, relating only to the clinic of generation and therefore not of direct relevance to the general population. What then is a prevalence rate? Within the individual clinics the prevalence rates are an expression of the number of patients with patch positive responses relative to a given

baseline clinical population. The choice of this baseline population varies from clinic to clinic and so therefore do the prevalence rates. As an example of how the prevalence rates vary with the choice of denominator, consider the following simple model. Figure 1 shows the schematic flow of patients presenting with dermatological problems to the dermatology clinics. If actual patient numbers (de Groot 1988) are now superimposed on this scheme we arrive at the situation shown in figure 2. Using as the denominator for our calculation of prevalence rates the total number of patients attending the clinic, the total number patch tested (suspected of contact allergic dermatitis) or the number diagnosed as suffering from cosmetic allergy we can calculate the prevalence rates shown in table 1. As you can see they vary by several orders of magnitude. If this exercise is repeated, for example, with the group of patients with positive patch test reactions to biocides we get a similar set of disparate results. This highlights one of the inherent problems in comparing data reported by different practitioners with that in the medical literature (Wooder and Koch 1988). In addition,



these prevalence rates relate only to the clinical population under study and not directly to the general public i.e. the measure of risk that we have comes not from the normal population but from patients patch-tested in the dermatology clinics. This obviously provides a biased population, as people only attend such clinics if they have skin problems, and the number of patch test positive reactions seen by dermatologists is bound to be greater than that you would expect to find in the normal population. Thus the high prevalence of positive patch-test reactions in patients attending dermatology clinics mean little more than the finding that there is a high prevalence of hyperglycemia/hypoglycemia in patients attending diabetes clinics. It is also of paramount importance that the public is educated to realise that a positive patch test to a particular allergen is not, of itself, proof that the current clinical conditions was caused by that allergen, i.e. whereas a

negative test does not necessarily mean that the patient has a sensitivity which is relevant to their current clinical problem. Relevance of positive patch-test reactions has become a major area of concern for those working in the field of contact dermatitis. The reason that many positive reactions are not relevant is that the elicitation of sensitisation is not all or none phenomenon. Like the majority of effects seen in pharmacology and toxicology, skin sensitisation shows clear dose response relationships. Thus although the patient may react to a chemical in a patch-test at a particular concentration, they may never react to the much lower concentrations that they are exposed to in every day life. In other words, the patch-test response gives the most pessimistic measure of risk rather than the actual risk.

Thus it would be helpful if the term prevalence was used in a more precise way, i.e. either by carefully defining on each occasion, the group

Table I

EFFECT OF DENOMINATOR ON PREVALENCE RATES

BIOCIDE	N° POSITIVE	TOTAL PATIENTS	SUSPECTED CAD	COSMETIC ALLERGY	BIOCIDE ALLERGY
Benzoxonium Chloride	1	0.006	0.07	2.04	10
Chloroacetamide	1	0.006	0.07	2.04	10
Formaldehyde	1	0.006	0.07	2.04	10
Imidazolidinyl Urea	1	0.006	0.07	2.04	10
Kathon CG	3	0.02	0.21	6.12	30
Parabens	1	0.006	0.07	2.04	10
Quaternium-15	2	0.012	0.14	4.08	20
DeGroot 1989					

to which it applies, and therefore the groups to which it does not apply, or better still agreeing a standardised definition that would allow genuine comparison of the valuable data from different clinics. In the same context I would also suggest that we need more information on the population prevalence rates. These additions, would I believe, greatly enhance good clinical and epidemiological practice.

Table II

EFFECT OF DENOMINATOR ON PREVALENCE RATES

CLASS OF INGREDIENT	N° POSITIVE	TOTAL PATIENTS	SUSPECTED CAD	COSMETIC ALLERGY
Fragrances	28	0.18	2.0	57
Biocides	10	0.06	0.71	20
Emulsifiers	4	0.03	0.3	8.16
Miscellaneous	9	0.06	0.64	18.37
DeGroot 1989				

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CONTACT ALLERGY TO PRESERVATIVES IN COSMETICS AND RELATIONSHIP TO THE DEGREE OF FORMALDEHYDE ALLERGY

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Received: October 26, 1989; **Presented at** 3rd International Congress on Cosmetic Dermatology "Progress in Cosmetic Dermatology" - 27 - 29th October 1989, Wien

Key words: Allergy; Formaldehyde; Formaldehyde Releasers; Cosmetics

Synopsis

In 6200 patch test series performed because of the tentative diagnosis "contact dermatitis" we found 497 (8.0%) positive patch test reactions to potential ingredients of cosmetics, 221 (3.6%) of them at all relevant and only 8 (0.1%) due to formaldehyde releasers (FR).

Test series with different formaldehyde concentrations and FR in 140 patients suffering from proven allergy to formaldehyde revealed:

The potential hazard of allergic side effects varies among the different FR and is correlated with the degree of formaldehyde sensitivity.

Riassunto

Nel tentativo di giungere ad una diagnosi certa si sono eseguiti 6.200 patch test predittivi.

497 (8%) delle risposte positive sono da addebitarsi a ingredienti cosmetici.

La reattività è molto evidente in 221 (3,6 %) patch test e soltanto 8 (0,1 %) risposte positive sono attribuibili a composti donatori di formaldeide. È stato, inoltre, rilevato che il grado di positività riscontrata per la presenza dei donatori di formaldeide è direttamente correlabile al grado di sensibilizzazione alla formaldeide dei soggetti esaminati.

Cosmetic-related allergies are the subject of numerous publications. So will only briefly present our epidemiological data, which is limited to emulsifiers and preservatives, and draw attention to possible correlations with the formaldehyde allergy.

7254 patients were patch tested because of a tentative diagnosis of "contact dermatitis or eczema", 5470 with the GDR-standard series, containing wool alcohols and parabens, and 620 with a special series (emulsifiers and preservatives); altogether 6200 patients were tested with potential ingredients of cosmetics.

In table 1 the statistical results from our computer stored data are summarized. The relevance was determined on the basis of case history and medical examination. This table shows two things: first the well known fact that side effects from additives are much more frequent in therapeutic preparations, applied to damaged skin and probably containing other powerful sensitizers, than in cosmetics. The relation 221:45, that is about 5:1, agreed with

other published experiences in this field.

Secondly we can see that the ranking list of such allergens depends on the frequency of performed tests and on the duration and amount of exposure. Parabens have for many years been the basic preservatives in nearly all vehicles of the oil in water-type, produced in the GDR.

Piasolan®, an imidazolidinyl urea like Germall®, has been used for about 10 years, Bronopol® and Kathon CG® since 1985. The "other preservatives" include sorbic acid, gallates and benzalconium chloride, up to now (1989) no Kathon CG®. From the 8 cosmetic-related allergies to formaldehyde releasers (FR) only 5 also showed a formaldehyde allergy. As these substances are no part of the standard series, a lot of sensitizations may have been undetected. On the other hand, formaldehyde has unquestionably been the major allergen in the GDR for many years, especially in young women, that is in persons who normally use a lot of cosmetics. So we considered whether cosmetic intolerance might be related to formaldehyde allergy.

Table I
POSITIVE PATCH TESTS

Emulsifiers Preservatives	total	relevant at all	cosmetic related
Wool alcohols	156	99	12
Other emulsifiers	27	18	5
Parabens	155	83	15
Formaldehyde-releaser	46	14	8
Other preservatives	13	7	5
Total	497	221	45
% of 6200 test series	8.0	3.6	0.7

In cooperation with Rothe and Zschunke from the Central Institute of Occupational Medicine in Berlin we tested this series (upper line) and in our department, moreover, these additional formaldehyde concentrations. In 20 patients, most of them with minor symptoms or a family history of atopy, repeated control tests revealed slight irritant reactions to the 1% and 0.7% preparations. It should be kept in mind that these generally recommended concentrations might give rise to false positive reactions in several cases. The vehicle of the FR (ungt. emuls. aquos.) is the o/w-emulsion of our pharmacopoeia and the basic vehicle in this type of cosmetic.

In the remaining 140 subjects, suffering from proven allergy to formaldehyde, confirmed by repeated patch testing and additionally by the case history and clinical pattern, we obtained these results:

Two aspects are of cosmetical interest.

1.: The potential hazard varies distinctly among the different FR. It is low for Bronopol®, somewhat higher for Germall® and Piasolan®, respectively, and clearly higher in Dowicil 200®. Grotan BK®, a biocide in cutting fluids, is the strongest allergen and clearly releases the most formaldehyde. Among these 3 preservatives the

amount of free formaldehyde in fresh and 3 month stored preparations, respectively, decreased from Dowicil 200®, set as 100%, to about 50% in Germall 115® and 20% in Bronopol®, as described by HABEL. This is the same order as in most other published ranking lists of contact allergies to cosmetics, for instance those by FISHER, DE GROOT or EIER-MANN. Though only a part of the allergies to such preservatives is coupled with a formaldehyde allergy, their sensitizing potency is obviously related to the amount of released formaldehyde.

2.: The frequency of positive tests due to FR is significantly correlated with the degree of hypersensitivity to formaldehyde ($p < 0.01$).

Hence it follows that especially in persons with highly marked hypersensitivity to formaldehyde FR in cosmetics are capable of provoking relapses of allergic dermatitis. But even these positive patch test reactions do not automatically imply an intolerance of cosmetics. Only 5 of the 66 allergic women, tested in Dresden, had a confirmed case history of contact dermatitis from skin care products containing FR. None had problems with rinse off products. So we believe, that patients with formaldehyde allergy, provided it is not an extreme one, need not com-

Table II

SUBSTANCES, CONCENTRATIONS AND VEHICLES USED IN PATCH TESTING:

Formaldehyde 0.7%, 0.35%, 0.2%, 0.05% w.
(additional in 86 patients from Dresden formaldehyde 1% pet., 1% and 0.1% w.)

Piasolan 2%, Dowicil 200 and Germall 115 1%,

Bronopol 0.25% in ungt.emuls.aquos.

Grotan BK 1% w.

pletely avoid cosmetics preserved by such chemicals. But to prevent adverse effects from possibly incorporated FR, they should perform a repeated open application test before using a new, unknown cosmetic.

Table III

Reactivity to FR	Degree of hypersensitivity to formaldehyde (% w)				Positive reactions
	0.7	0.35	0.2	0.05	total
Bronopol		1	1	3	5
Germall 115		2	5	2	9
Piasolan		2	7	4	13
Dowicil 200	1	4	16	14	35
Grotan BK	3	14	42	19	78
FR negative	17	23	11	0	-
No. of subjects	21	40	59	20	140

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2

Every day Problems in Dermatology:
The Cosmetic Connection

2nd International Meeting on
Cosmetic Dermatology,
Rome, Italy: May 19-22, 1987



Edited By: P. Morganti, F.J.G. Ebling

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Volume 2

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Editors: P. Morganti, F.J.G. Ebling

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Announcement

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PRELIMINARY PROGRAM PROGRAMMA PRELIMINARE

OCTOBER 31th THURSDAY / GIOVEDÌ 31 OTTOBRE

- 09.00 - *General considerations* / Considerazioni generali (C. Jacobson - U.S.A.)
- 09.30 - *Opening remarks* / Note introduttive (P. Morganti - I)
- 09.45 - *Cosmetic preparation: state of the art* / I prodotti cosmetici: stato dell'arte
- 10.00 - *Safety evaluation of cosmetic ingredients in the European Community and in other countries* / Valutazione della sicurezza degli ingredienti cosmetici nella CEE e negli altri paesi (N. Loprieno - I)
- 10.15 - *Role of lipids in biological membranes* / Ruolo dei lipidi nelle membrane biologiche (B. Berra - I)
- 10.30 - *Advances in percutaneous absorption* / L'assorbimento percutaneo secondo le più recenti acquisizioni (W. Shalla - D)
- 10.45 - *Liposomes: future prospects and alternative solutions* / I liposomi: prospettive future e soluzioni alternative (G. Gregoriades - U.K.)
- 11.00 - *Break*
- 11.15 - *Pediatric cosmetology: current and future trends* / La cosmesi della prima età: oggi e domani (C. Jacobson - U.S.A.)
- 11.30 - *Social role of cosmetics in elderly people* / Ruolo sociale dei cosmetici nella terza età (A. Tosti - I)
- 11.45 - *Cosmetic dermatology and mucous membranes* / Cosmesi dermatologica e mucose (S. Mancuso - I)
- 12.00 - *EEC cosmetic ingredients and labeling* / L'etichettatura degli ingredienti cosmetici (De Giuli - I)
- 12.15 - *Quality control to protect EEC consumer* / Il controllo qualità a difesa del consumatore (L. Gagliardi - I)
- 13.00 - *Brunch*

SKIN SURFACE AND PERMEATION / CUTE E ASSORBIMENTO

- 14.00 - *Liposomes as natural-like membranes* / I liposomi quali membrane naturali simili
- 14.15 - *Liposomes as topic carriers: progress working* / I liposomi come carrier per uso topico: prospettive e realtà (G. Gregoriades - U.K.)
- 14.30 - *Function and stability of liposomes as cosmetic vehicles* / Funzione e stabilità dei liposomi come veicoli cosmetici (E. Menegatti - I)
- 14.45 - *New biodegradable and biocompatible capsules for the cosmetic industry: the collaspheres* / Le nuove capsule biodegradabili e biocompatibili per l'industria cosmetica: le collasphere (A. Huc - F)
- 15.00 - *Discussion* / Discussione
- 15.30 - *The choice of vehicles in cosmetic dermatology* / L'importanza dei veicoli nella dermatologia cosmetologica (B. James - U.S.A.)
- 15.45 - *Activity of vehicles and diffusion through the horny layer* / Attività dei veicoli e loro diffusione attraverso lo strato corneo (W. Shalla - D)
- 16.00 - *Skin permeability in infants and young children* / Permeabilità cutanea nella prima infanzia e nella pubertà (C. Jacobson - U.S.A.)
- 16.15 - *Skin permeability in elderly people* / La permeabilità cutanea nell'anziano (F. Kerdel Vegas - YV)
- 16.30 - *Permeability of buccal mucosa membranes* / La permeabilità della mucosa orale (A. Jarret - U.K.)
- 16.45 - *Permeability of vaginal mucosa surfaces* / Permeabilità ed assorbimento della membrana vaginale (S. Mancuso - I)
- 17.00 - *Discussion* / Discussione
- 17.15 - *Break*

**ACTIVE COSMETIC COMPOUNDS FOR ELDERLY SKIN
I PRINCIPI ATTIVI PER LA CUTE INVECCHIATA**

- 17.30 - *Photophysiology of dry skin and treatment* / Patofisiologia e trattamento della cute secca (M. W. Greaves - U.K.)
17.45 - *Topical use of retinoic acid in aged and stressed skin* / L'uso topico dell'acido retinoico nella cute invecchiata (W. Raab - A.)
18.00 - *"Prolonged and controlled release of cosmetic dermatologic actives with a submicronic polymeric lattice: nanospheres 100®"* / Controllo e realizzazione dei principi attivi cosmetici con lattice submicroscopico: nanosphere 100® (J. Caillon - F.)
18.15 - *Vitamin derivatives in aged skin* / Le vitamine quali principi attivi per l'invecchiamento cutaneo (D. Djerassi - U.S.A.)
18.30 - *Effects of collagen on skin surface* / Gli effetti del collagene sulla cute invecchiata
18.45 - *Discussion* / Discussione
20.30 - *Benvenue cocktail* / Cocktail di benvenuto

NOVEMBER 1st FRIDAY / VENERDI' 1 NOVEMBRE

COSMETIC PRESERVATION / LA CONSERVAZIONE DEI PRODOTTI COSMETICI

- 09.00 - *The role of preservatives in controlling microbial contamination introduced in the manufacture of cosmetics* / Contaminazione batterica e conservanti (E. F. W. Warwick - U.S.A.)
09.15 - *Aspects on biocide use* / Aspetti tecnici sull'uso dei conservanti (K. H. Diehl - D.)
09.30 - *Parabens today* / I parabeni oggi (Kranbar - U.S.A.)
09.45 - *Substituted imidazolidinyl urea compounds* / Imidazolidinyl urea e derivati (W. E. Roses - U.S.A.)
10.00 - *Food-grade ingredients as preservatives* / Conservanti di grado alimentare (J. J. Kabara - U.S.A.)
10.30 - *New phospholipids as preservatives: an update* / L'uso dei fosfolipidi come conservanti (J. I. Yablonski, D. Fost - U.S.A.)
10.45 - *Skin irritation and sensitization caused by preservatives* / Irritazioni e sensibilizzazioni provocate dai conservanti (K. E. Andersen - D.)
11.00 - *Toxicity of preservatives* / La tossicità dei conservanti (H. F. Kemper - D.)
11.15 - *Discussion* / Discussione
11.30 - *Brunch*
13.00 - *Bus to Casamari (famous gothic church)* / Autobus per l'abbazia di Casamari

NOVEMBER 2nd SATURDAY / SABATO 2 NOVEMBRE

COSMETIC DISTRIBUTION / LA DISTRIBUZIONE DEI COSMETICI

- 09.15 - *Legal implications of selective channel distribution* / Problemi giuridici connessi con la distribuzione di canali selettivi (F. Terenzi - I.)
09.30 - *Channeling distribution of cosmetic products in Italy* / La distribuzione dei cosmetici in Italia nei differenti canali (E. Chiaccherini - I.)
09.45 - *F.O.F.I. direction of pharmacy cosmetic products* / Orientamenti della F.O.F.I. sui problemi riguardanti il comparto "cosmetici in farmacia" (G. Leopardi)
10.00 - *Italian Feder. Farma directions on dermocosmetics* / Orientamenti della Feder. Farma sul comparto dermocosmetico (A. Ambrecht - I.)
10.15 - *Cosmetic market in pharmacy: a national enquire* / Il mercato dermocosmetico in farmacia: indagine nazionale UTIFAR (L. Casanova - I.)
10.30 - *Pharmacy distribution of cosmetic products* / La distribuzione dei cosmetici in farmacia (Maganelli - I.)
10.45 - *Discussion* / Discussione
11.15 - *Break*

**LEGAL AND PROFESSIONAL RESPONSABILITIES
RESPONSABILITÀ CIVILE E IMPLICAZIONI LEGALI**

- 11.30 - *Legal liability of cosmetic producers to the public* / La responsabilità civile del produttore di cosmetici (A. Iannini - I.)
11.45 - *Legal liability of physicians as cosmetic products prescribers to the public* / La responsabilità civile del medico quale prescrittore di cosmetici (M. Rota Muscardin - I.)
12.00 - *Legal liability of pharmacist as cosmetic products dealers to the public* / La responsabilità civile del farmacista quale distributore (M. Marchetti - I.)
12.15 - *Misleading and correct advertising* / Pubblicità ingannevole e pubblicità corretta (Masi - I.)
12.30 - *Low protection of EEC consumer* / La tutela giuridica del consumatore europeo
12.45 - *Discussion* / Discussione
13.15 - *Brunch*
14.45 / 18.00 - *Free communications* / Comunicazioni libere

FREE COMMUNICATIONS / COMUNICAZIONI LIBERE:

*Abstract of works related to the main topics of the meeting can be submitted to the Scientific Secretariat **before July 15, 1991**. Abstract should be written in English on the abstract form which is enclosed to the preliminary programme.*

I lavori relativi agli argomenti principali del Convegno debbono essere inviati alla Segreteria Scientifica entro il 5 Luglio 1991. Il testo del lavoro dovrà essere in inglese e redatto sull'apposito modulo che accompagna il presente programma preliminare.

INSCRIPTION FEES / TERMINI DI ISCRIZIONE:

Before July 15th, 1991 £ 650.000 Italian Lire - After July 15th, 1991 £ 850.000 Italian Lire.

Entro il 15 Luglio, 1991 Lit. 650.000 - Dopo il 15 Luglio, 1991 Lit. 850.000.

ORGANIZING SECRETARIAT / SEGRETERIA ORGANIZZATIVA

GIBI Studio Congressi

Via Marco Besso, 40 - 00191 - ROMA (Italy)
Tel. 06/32.73.291-32.86.478 Telefax: 06/32.76.288

SCIENTIFIC SECRETARIAT / SEGRETERIA SCIENTIFICA

International Society of Cosmetic Dermatology

Via Innocenzo XI, 41 - 00165 - ROMA (Italy)
Tel. 06/63.78.788 Telefax: 06/63.80.839 Telex: 621100 (address) \ KNM =

IV INTERNATIONAL MEETING ON COSMETIC DERMATOLOGY
PROGRESS IN COSMETIC DERMATOLOGY: SCIENCE AND SAFETY

October 30 - November 2, 1991 - Villa MIANI - ROME - ITALY

MODULO DI PRENOTAZIONE ALBERGHIERA

Il presente modulo, con il deposito richiesto, dovrà essere inviato al più presto a:
GIBI Studio Congressi - Via Marco Besso, 40 - 00191 ROMA - Tel. (06) 3273291 - 3286478 - Fax 3276288

(prego compilare a macchina o in stampatello)

Cognome Nome

Indirizzo

c.a.p. Città Tel.

Condizioni:

- I prezzi si intendono per camera, per notte e includono la prima colazione o la mezza pensione
- Tutte le camere hanno servizi privati
- La richiesta di prenotazione dovrà pervenire il più presto possibile e dovrà essere accompagnata da un deposito pari al costo della prima notte più Lit. 15.000 a camera per spese di prenotazione
- Per eventuali cancellazioni che perverranno entro il 27 giugno '91 saranno addebitate le sole spese di prenotazione, dopo tale data sarà addebitata anche la prima notte

	Camera e piccola colazione	Mezza pensione
☐ Hotel Hilton (1 ^a cat. lusso)		
☐ camera singola	☐ 260.000	☐ 329.000
☐ camera doppia	☐ 342.000	☐ 480.000
☐ camera doppia uso singola	☐ 301.000	☐ 370.000
☐ Hotel Clodio (2 ^a cat.)		
☐ camera doppia	☐ 220.000	☐ 290.000
☐ camera doppia uso singola	☐ 179.000	☐ 214.000
☐ Hotel Olympic (2 ^a cat.)		
☐ camera singola	☐ 170.000	
☐ camera doppia	☐ 210.000	

Vi richiedo di prenotare n. camera(e) su specificata(e) con arrivo il giorno
e partenza il giorno Allego il deposito della prima notte più Lit. 15.000 a camera a mezzo assegno
n. della banca per un importo di Lit.

N.B. - Le camere singole sono in numero limitato e potranno essere assegnate solo alle prime prenotazioni.

Note

Data Firma

IV INTERNATIONAL MEETING ON COSMETIC DERMATOLOGY
PROGRESS IN COSMETIC DERMATOLOGY: SCIENCE AND SAFETY

October 30 - November 2 , 1991 - Villa MIANI - ROME - ITALY

HOTEL RESERVATION FORM

Please type or print using block letters and return to:

GIBI Studio Congressi - Via Marco Besso, 40 - 00191 ROMA - Tel. (06) 3273291 - 3286478 - Fax 3276288

Surname Name

Address Country

Zip code City Tel.No

Conditions:

- Prices are per room, per night and include bed and breakfast or half board service
- This reservation form should reach GIBI Studio Congressi as soon as possible
- First night deposit plus Lit. 15.000 as agency fee are required at the moment of reservation
The deposit will be deducted from the hotel bill upon departure
- Request for cancellations must be received before July 27, 1991. For cancellations received before July 27 only the agency fee will be charged. After this date also the first night deposit will be charged

	Bed and breakfast	Half board
☐ Hotel Hilton (1 ^a cat. Luxury)		
☐ single room	☐ 260.000	☐ 329.000
☐ double room	☐ 342.000	☐ 480.000
☐ double room for single use	☐ 301.000	☐ 370.000
☐ Hotel Clodio (2 ^a cat.)		
☐ double room	☐ 220.000	☐ 290.000
☐ double room for single use	☐ 179.000	☐ 214.000
☐ Hotel Olympic (2 ^a cat.)		
☐ single room	☐ 170.000	
☐ double room	☐ 210.000	

Please reserve n. room(s) arrival date departure date

I enclose first night deposit plus Lit. 15.000 per room with check n..... Bank.....
of Lit.

N.B. - As single rooms are very few they will be assigned on first come, first served basis.

Note.....

Date Signature.....

IV INTERNATIONAL MEETING ON COSMETIC DERMATOLOGY
PROGRESS IN COSMETIC DERMATOLOGY: SCIENCE AND SAFETY

October 30 - November 2 , 1991 - Villa MIANI - ROME - ITALY

SCHEDA DI ISCRIZIONE

Cognome Nome

Indirizzo
(dell'intestatario della fattura)

c.a.p. Città

Telefono C.F. - P. IVA
(dell'intestatario della fattura)

Quota di iscrizione: entro il 15 luglio Lit. 650.000 dopo il 15 luglio Lit. 850.000

La scheda con allegato assegno o vaglia postale intestato a GIBI Studio Congressi, dovranno essere inviati alla Segreteria Organizzativa: GIBI Studio Congressi - Via Marco Besso, 40 - 00191 ROMA - Tel. (06) 3273291 - 3286478 - Fax 3276288

Allegato assegno/vaglia n. della Banca

di Lit.

Data Firma

IV INTERNATIONAL MEETING ON COSMETIC DERMATOLOGY
PROGRESS IN COSMETIC DERMATOLOGY: SCIENCE AND SAFETY

October 30 - November 2 , 1991 - Villa MIANI - ROME - ITALY

REGISTRATION FORM

Surname Name

Address

Zip Code City

Country

Telephone No

Registration fee: before July 15 Lit. 650.000 after July 15 Lit. 850.000

This form, duly filled in and signed, with check at the order of GIBI Studio Congressi, must be sent to the Organizing Secretariat: GIBI Studio Congressi - Via Marco Besso, 40 - 00191 ROMA - Tel. (06) 3273291 - 3286478 - Fax 3276288

I enclose check n. Bank

of Italian Lire

Date Signature

PROGRESS IN COSMETIC DERMATOLOGY: SCIENCE AND SAFETY

Riassunto (solo in lingua Inglese) Abstract Reproduction Form (English language only)

Trascrivere il riassunto nel rettangolo / *Type abstract within the rectangle.*

Per ulteriori informazioni leggere le indicazioni sul retro / *For further information see directions on next page*

Titolo
Title —

Autore
Author —

Riassunto
Abstract —

Indicazioni / Directions

- Titolo del lavoro - con lettere maiuscole.
Title of paper - in capital letters.
- Nome degli autori - in maiuscolo e minuscolo, con il nome del relatore sottolineato.
Name of author(s) - in upper and lower case, with name of presenter underlined.
- Nome del dipartimento / ospedale / organizzazione / città - in maiuscolo e minuscolo.
Name of department / hospital / organisation / town / country - in upper and lower case.
- Interlinea 2.
Leave one line space.
- Utilizza una macchina da scrivere elettronica.
Use an electric typewriter with plastic black ribbon only.
- Il testo apparirà sul libro degli abstract come verrà inviato e gli eventuali errori rimarranno visibili.
Your text will appear in the book of abstract exactly as you send it and every error or imperfection will be visible.
- **Ultima data di ricevimento per il riassunto: 15 Luglio 1991**
Deadline for receipt of abstract: July 15, 1991
- **Rispedire il riassunto a: / Please return the abstract to:**
P. Morganti, Via innocenzo XI, 41 - 00165 Roma (Italy)

NAME OF PRESENTER / NOME DEL RELATORE

Nome / Name _____

Ospedale / Hospital - Organizzazione / Organisation _____

Indirizzo / Address _____

Città / Town _____ Nazione / Country _____

Telefono / Telephone _____ Telex _____ Telefax _____

18TH WORLD CONGRESS OF DERMATOLOGY

Scholarships Available for the 18th World Congress of Dermatology

The 18th World Congress of Dermatology will take place in New York City from June 12-18, 1992. In an effort to encourage the participation of young dermatologists, the Congress will award a limited number of scholarships, as follows:

Dermatologists from Developing Countries: Applicants must be no older than 38 years of age at the time of the Congress. The scholarship will provide complimentary registration and hotel accommodations (two awardees to a room), and a moderate subsistence allowance. Awards are competitive and are contingent on sponsorship by one's national society. Abstract submission is mandatory. Obtain further information and application forms from your national society before June 1, 1991.

Dermatologists from Developed Countries: Applicant must be a Resident or Fellow in a full-time training program. The Scholarship will provide complimentary registration and a small subsistence allowance. A letter from the educational or training institution validating the applicant's status must be submitted with the application form. Abstract submission is mandatory.

Forms are available from the 18th World Congress Secretariat,
875 Kings Highway, W. Deptford, NJ 08096, USA.

Call for Abstracts for the 18th World Congress of Dermatology

The 18th World Congress of Dermatology Organizing Committee and the International League of Dermatological Societies invite the submission of abstracts for short communications to be presented at the 18th World Congress, June 12-18, 1992, New York City. Selected abstracts will be presented in the following sessions:

- **Case Presentations** - Four-minute presentations of clinical cases of exceptional scientific and/or educational interest.
- **Contributions to Clinical and Experimental Dermatology**

Oral presentations of original contributions of clinical, therapeutic or laboratory investigations.

Poster presentations of original contributions to clinical and laboratory investigation which can be effectively displayed by illustrative material (graphs, charts and tables). Authors are to be present during specified times for discussion of the posted material.

Abstracts must be submitted on the official Congress Abstract Reproduction Form and received before August 1, 1991.

Forms and submission guidelines are available from the 18th World Congress Secretariat,
875 Kings Highway, W. Deptford, NJ 08096, USA.

Chiuso in Tipografia: 22 Luglio 1991

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