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Journal of the Society of Cosmetic Chemists

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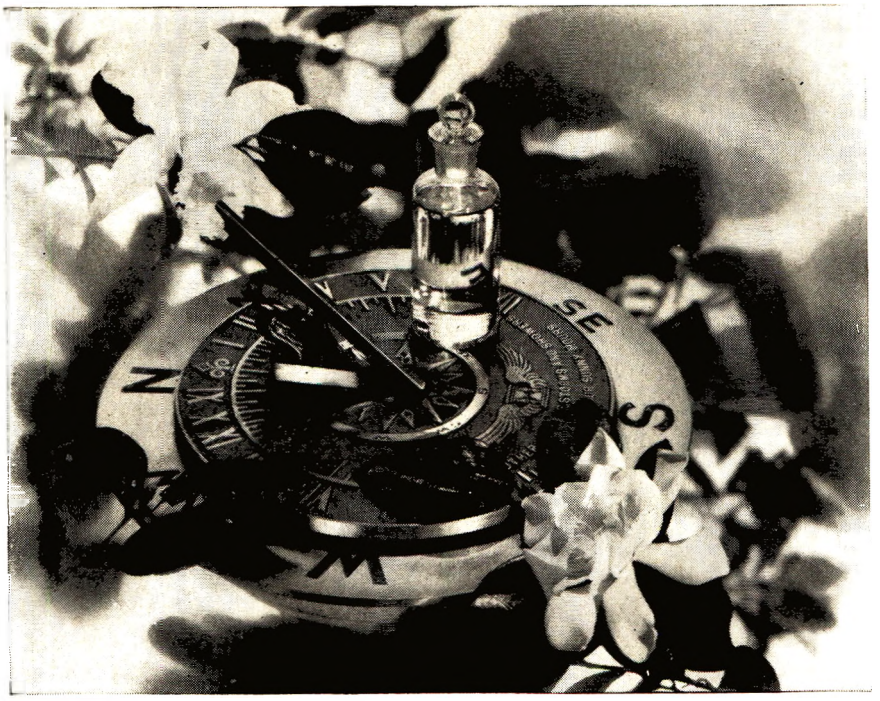

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Journal of the Society of Cosmetic Chemists

VOLUME XVI • NUMBER 2

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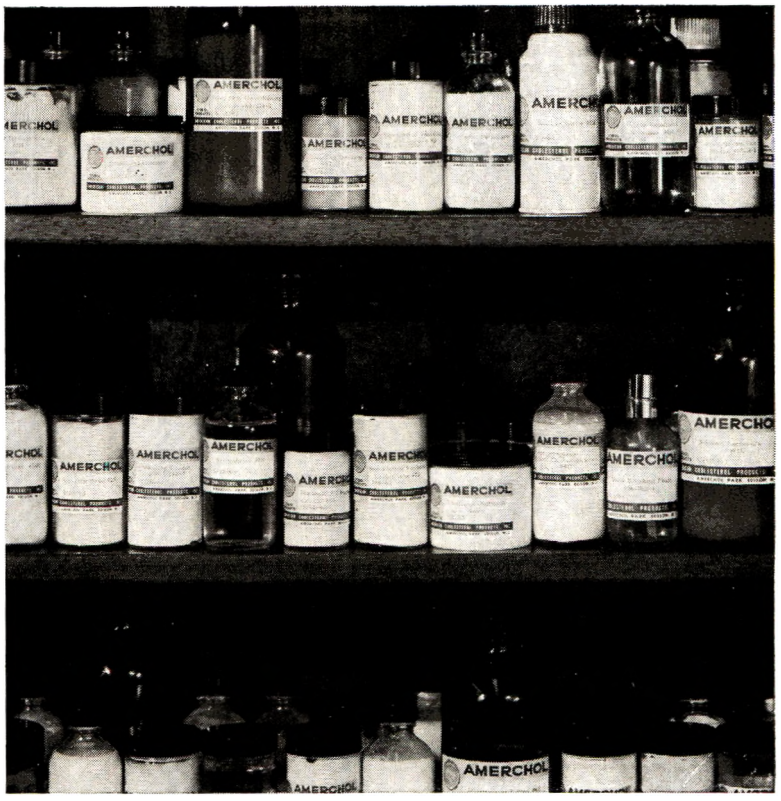

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International Federation of Societies of Cosmetic Chemists

The Fourth Congress of the I. F. S. C. C. will take place in Paris in June, 1966.

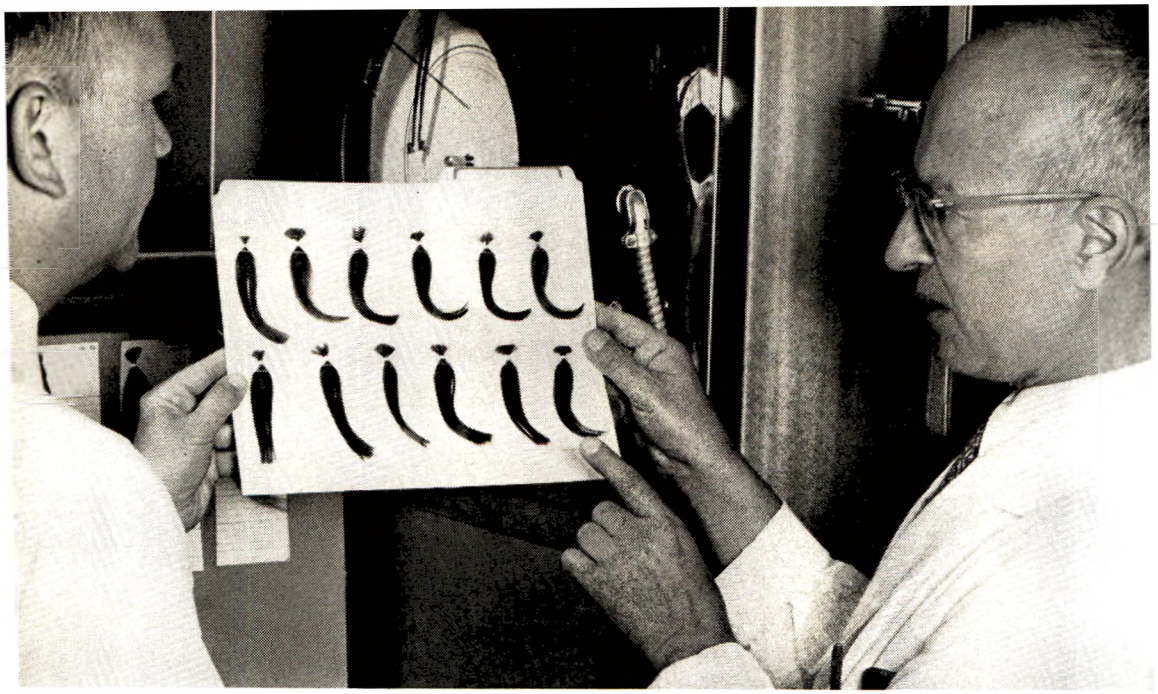
The "Société Francaise de Cosmetologie" has created a scientific Committee consisting of:

Dr. Ir. Velon
Ir. Jean Morelle
Dr. Collin

This Committee wishes to receive conference papers before January 31, 1966.

Each paper can be typed in the original language of the speaker. The French Committee will take care of the translation in English, French and German.

General Secretary
Dr. P. A. M. E. van Velzen
Scheveningseweg 62
The Hague, The Netherlands



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INDEX TO ADVERTISERS

SYNOPSES FOR CARD INDEXES

The following synopses can be cut out and mounted on 3 × 5 in. index cards for reference, without mutilating the pages of the Journal.

A simple U.V. absorptimeter for the estimation of certain nonionic emulsifiers and other aromatic compounds: D. E. Herring. *Journal of the Society of Cosmetic Chemists* 16, 79 (1965)

Synopsis—The construction and circuitry of an inexpensive U.V. absorptimeter are described. It is shown that this simple instrument is useful for the estimation and detection of emulsifiers and other compounds showing U.V. absorption.

The role of government in the field of cosmetics: Vincent A. Kleinfeld. *Journal of the Society of Cosmetic Chemists* 16, 85 (1965)

Synopsis—The wide distribution and vital importance of cosmetics to women raises some serious problems in the marketing of cosmetics. A limited number of persons may experience an unforeseeable reaction to virtually every cosmetic, and it is not feasible to specify a rigid series of tests which will disclose the possible incidence of injury caused by all cosmetics. Instead each new preparation must be subjected to tests designed by experts.

The majority of cosmetic manufacturers conduct careful scientific tests before their products are marketed. However, some have not observed the necessary precautions, seek to obtain an unfair competitive advantage, and have caused the enactment of regulatory legislation. In the 1938 Federal Food, Drug and Cosmetic Act, Congress set forth the circumstances under which a cosmetic shall be deemed adulterated and misbranded, and severe penalties for violations were provided.

Notwithstanding this, injuries occurred, and, in view of the public demand for greater protection, new legislation appears inevitable. The important question is how far one wishes to go in affording additional protection to the consumer. This depends, in large part, on one's theory of government. A statute can be devised which will place the industry in a strait jacket so that most old cosmetics will be regulated out of existence and virtually no new ones will appear. It would appear advisable, instead, to provide for the pretesting of new cosmetics or of their ingredients before the cosmetics are placed on the market. More stringent legislation may adversely affect the public as well as the industry.

Public safety and the cosmetic chemist—a European review: J. B. Wilkinson and G. Carrière. *Journal of the Society of Cosmetic Chemists* 16, 91 (1965).

Synopsis—The cosmetic industry's position concerning legislation involving toilet preparations and cosmetics in European countries is reviewed. The proposals of the European Committee on Chronic Toxicity Hazards (Eurotox) are discussed, and the I.F.S.C.C. policy toward positive and negative lists of cosmetic ingredients is reviewed in the light of these considerations. Some salient features of legislation in various countries, which may affect the formulation and marketing of cosmetics, are pointed out in the appendices.

Placement of bromo acids in lipsticks by water-soluble FDC and DC colors: Hermann Wilmsmann. *Journal of the Society of Cosmetic Chemists* 16, 105 (1965)

Synopsis—Water-soluble FDC and DC colors have found almost no application in lipsticks because of their insolubility in the usual lipstick bases and because they have no tendency to stain lips. It has now been found that the free sulfonic acids prepared from the FDC and DC colors have satisfactory solubility in fatty bases and produce adequate stain on the lips. It is shown that these dyes can be readily incorporated into a conventional lipstick base and that it is possible to create a fairly wide range of shades through exclusive use of FDC and DC azocolor acids.

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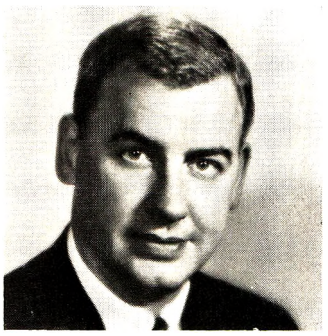
President



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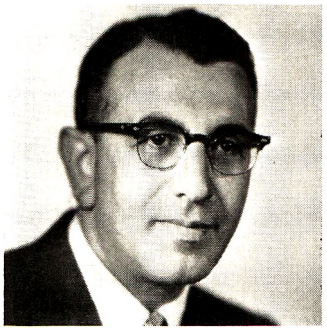

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J. Soc. Cosmetic Chemists, 16, 59–62(1965)

Annual Report of the President Robert A. Kramer

December 22, 1964

In making my Annual Report to you as your Nineteenth President—the twentieth year for the Society of Cosmetic Chemists—let me look back for a few minutes and see where we came from.

In 1935, well before the Food, Drug and Cosmetic Act of 1938, Maison deNavarre first attempted to get a few cosmetic chemists to join him in the formation of a Society that would bring some recognition in the scientific field to chemists working in the cosmetic industry. After ten years of frustration, eleven chemists were finally willing to join him, and they then pioneered in the formation of our Society in 1945. Father Time and retirement have taken their toll, but we are honored in having at least five of the original twelve at today's meeting. The Charter Members are: Philip Adams, James Baker (present), Robert Casely, M. G. deNavarre (present), Emery A. Emerson, Emanual G. Gundlach, Emil G. Klarmann (deceased), Stephen A. Karas (present), Raymond Reed, Marcel Suter (present), Walter Taylor (present), and Cloyce L. Thomas.

We owe much to these charter members because their foresight and efforts paved the way for the success of our Society in the U.S.A. as well as for the twelve other Cosmetic Chemist Societies in various countries of the world.

Today there are close to 2000 members in the thirteen autonomous societies associated with the International Federation of Societies of Cosmetic Chemists. Of the 950 members in the U.S.A., well over 100 of them actively participated in the affairs of your Society as officers, directors or committeemen in 1964.

All of this splendid crew deserve credit for keeping our ship in perfect trim, but time does not permit me at this moment to thank each one personally. However, I should like to take time to single out a few for special attention and to thank them sincerely for their efforts.

The Advisory Committee, under that master navigator, Lester Conrad, aided by six other past Presidents, for their recommendations to the Board of Directors, which kept us on a true course all year.

The Awards and Recognition Committee of five under John Longfellow for their guidance; the Literature Review Committee of ten under Willard Somerville for their monumental task of screening; and the Literature Award Committee of eight under Robert Goldemberg in the selection of Dr. E. Howard Mercer of Australian National University in Canberra, Australia, as the recipient of our Literature Award, which carried with it a $1000 honorarium and a trip to New York to receive it. Dr. Mercer's paper was on the "Biology of Keratin and of the Keratinization Process."

The Chapter Award Committee under Alfred Shansky for their selection of Dr. Peter Bartells of the Leitz Company to receive the first Chapter Award for his paper entitled "Quantitative Microscopy in the Cosmetic Industry." The New York Chapter recently made the presentation, which carried with it an honorarium of $250.

The Publication Committee under Martin Rieger and the eleven members who assisted him in handling one of the heaviest workloads in our Society, the JOURNAL of the SCC, for years our best source of income.

And thanks also to Martin Rieger's Publication Committee for their selection of the first recipients of the IFF Award given today at our luncheon to Drs. Coffey, Finkelstein and Laden of the Toni Company for their article entitled "The Effect of U.V. Irradiation on Enzyme Systems in the Epidermis." The IFF Award carries with it a $1000 honorarium and is sponsored by International Flavors and Fragrances, Inc.

The Medal Award Committee of five under the direction of Paul Lauffer deserves our most heartfelt appreciation and approbation for the selection of Harold Goulden, Scientific Director of the Toilet Goods Association, as the 1964 recipient.

The By-Laws Committee under James Baker for the important changes in our by-laws, which were approved by the Internal Revenue Service. And our sincere thanks to the Chapter Chairmen: E. J. Karolyi, California Chapter; William Ackley, Chicago Chapter; Winthrop Lange, New England Chapter; and Henry Maso, New York Chapter, for maintaining so much interest in Society affairs at the local level.

The Education Committee of three under William Mueller, for their excellent programs.

The Finance Committee of four under Paul Jewel; the three Investment Trustees under Jerry Amsterdam; and our Treasurer, Richard Faust, for keeping us more solvent than ever with a net worth just under $140,000.

The Membership Committee of five under Milton Schwarz for their conscientious efforts in screening applicants and selecting 80 new members in 1964.

To Robert Swaine and Samuel Cohen for that all-important task of arranging today's Scientific Meeting, luncheon and banquet.

To Sophie Plechner and her Nominating Committee, who gave us a slate of candidates that resulted, for the first time in our history, in each of our four Chapters having a member in 1965 as an officer in the National Society—Paul Jewel, President, is from California; William Mueller, President-Elect, is from Chicago; Robert Swaine, Treasurer, is from New England; and Harry Isacoff, Secretary, is from New York.

We were fortunate indeed this year to have one of our members, Sab Strianse, as President of the International Federation of Societies of Cosmetic Chemists. He was also Chairman of our International Affairs Committee. He directed a number of international committee meetings at the Third Congress of the IFSCC, which was held at Columbia University in June of this year. This Congress was by far the largest undertaking ever sponsored by any group of cosmetic chemists. We had 809 registrants from 22 countries, of whom 325 came from countries other than the U.S.A.

Mr. deNavarre, our first President, and also the first President of the IFSCC, headed the Scientific Committee that brought together scientists from all over the world to present papers at the Congress.

George Kolar headed the Fund-Raising Committee that raised over $29,000. That fund covered a mighty big share of the $71,000 expenses we had in connection with the Congress. Total receipts were $74,000, so we managed to come out in the black.

I am deeply indebted to Lester Conrad and Warren Dennis for the wonderful support they gave me on the Organizing Committee during the several years of planning that led to the success of the Congress.

Those of you who attended the Congress should long remember what Edward Morrish did in arranging the United Nations Dinner; Vincent deGennaro and his thrilling Boat Trip together with a boatside view of the most spectacular fireworks the City of New York has ever seen; Lester Conrad for that most fabulous Banquet; James Baker for those entertaining hours at the World's Fair Hawaiian Pavilion;

Agnes Korte for the thankless task of being the House Mother to 452 of our registrants who boarded at Columbia University during the Congress; Edward Silkin for that excellent public relations job; and last but not least, the man who carried the biggest load of all as Activities Committee Chairman and who kept the Congress running smoothly at all times, with the assistance of no less than twenty committeemen, Harry Isacoff.

We are indeed indebted to all of our Officers and Directors who gave so freely of their time. Paul Jewel had, in addition to his duties as President-Elect, the task of organizing the annual seminar which will be held in Los Angeles in September, 1965. Part of his plan is to have a tour group come from the East Coast and after attending the Seminar in Los Angeles go on to Mexico City to attend the Scientific Meeting which will be arranged by our friends just South of the Border.

Both our Secretary, Richard Lehne, and Treasurer, Richard Faust, are retiring from office this year after several years of very devoted service to your Society. We are greatly indebted to them for the vast amount of time they spent in the interests of our Society.

The staff at the New York Academy of Sciences under the direction of Eunice Miner has served us so well for so many years that we just cannot thank them enough.

And may I just say one word of appreciation to the person who made the greatest sacrifices so that I could devote so much time this year to your Society: my beloved wife, Lucile.

Now that my term grows to an end, I am most pleased to recognize officially and introduce to you the Officers and Directors you have chosen to serve your Society in 1965:

President, Paul Jewel; President-Elect, William Mueller; Secretary, Harry Isacoff; and Treasurer, Robert Swaine.

Directors for two years: Richard Lehne and Martin Rieger.

Directors serving the balance of their terms: M. G. deNavarre and Robert L. Goldemberg.

Paul Jewel, it is an honor for me to present you with this gavel and to install you and your fellow Officers and Directors for 1965. Congratulations and best wishes for success during your term of office.

J. Soc. Cosmetic Chemists, 16, 63–72(1965)

The Fifteenth Medal Award

December 2, 1964

Hotel Biltmore, New York City

Mr. Harold D. Goulden, Scientific Director of The Toilet Goods Association, was honored by the Society of Cosmetic Chemists for his scientific achievements and for his services to the cosmetic industry. Mr. Goulden received the Medal of the Society during its annual Dinner-Dance.

Mr. Edward Morrish acted as toastmaster during the evening's festivities. Dr. Paul G. I. Lauffer, winner of the thirteenth Medal Award, was the eulogist, and Mr. Robert Kramer, as President of the Society, presented the medal with the following citation:

HAROLD D. GOULDEN

> In recognition of your manifold and devoted services to the cosmetic industry;
>
> In gratitude for your constant and effective influence in advancing the status of the cosmetic chemist;
>
> In appreciation of your skillful presentation of scientific data;
>
> In acknowledgment of your untiring campaign to enable the cosmetic industry to cooperate harmoniously with all regulatory agencies;
>
> In remembrance of your vast contribution to the compilation of essential standards, handbooks and technical reports;

I present to you this Medal, our highest award for outstanding contributions to the art and science of cosmetics.

Harold DeWitt Goulden

EULOGY BY PAUL G. I. LAUFFER, PH.D.*

We are here this evening to honor Hal Goulden because he has made extraordinary and unique contributions to the welfare of the cosmetic industry and to the status of cosmetic chemists. He has done this by working hard and unselfishly and by applying to his tasks a keen intelligence, implemented and buttressed by sound training and experience.

Hard work was never a stranger to Hal. As a high school boy he delivered papers and worked as a printer's devil and as a clerk in a haberdashery store. His first connection with the toilet goods industry may have been his ordertaking for the old Larkin Company. Or it may have been his job in the greenhouse of Mr. Palmer, president of E. R. Squibb & Sons, who had an estate at the end of the street in Stamford where Hal lived. Mr. Palmer took an interest in his young assistant and took him along on walks through his large garden. He presented to Hal over a hundred fine rose plants, and Hal used their flowers, under the encouragement of his chemistry teacher, to prepare rose absolutes by enfleurage and by solvent extraction.

The same chemistry teacher, Dr. Parks, used to invite a small group of his students to spend evenings listening to his wireless set, using one of the first DeForest audiotrons. Hal has never forgotten the night when he watched Dr. Parks writing down the Morse Code message telling of the Titanic's sinking after she struck an iceberg. On another occasion, a lot of garbled code came in, and they did not know until the next day that the U. S. had attacked Vera Cruz.

One of Hal's first loves was football, which he played well as a boy, account of his speed (he later ran the 100 yards in 10 seconds flat when at Rutgers). However, while still in grammar school he was indulging one afternoon in his favorite game, and, as he dove in for a tackle, he got kicked right between the eyes. The other lads carried him home and deposited him on a bed, and when Hal's father came home and saw Hal's condition the football career ended then and there. Hal also

* Chesebrough-Pond's, Stamford, Conn.

sang the soprano solos at St. Andrew's Episcopal Church in Stamford at that time, and the choir master complained bitterly about his standing up there with a black eye to sing his solo. His mother rejoined that he was really a very good boy, and the choir master agreed that no doubt he was and might wear a halo, but it probably was an asbestos one.

At Rutgers, Hal was both treasurer and steward of the Kappa Sigma fraternity. There he ran the dining room where 40 hungry students ate 21 meals a week. He put to good use the training he had received when he spent several summers with his grandfather who ran a restaurant in Waterbury; there Hal arose at 5 a.m. to make the rounds of wholesale houses with his grandfather and learned a lot about buying food.

One day at Rutgers, a frat brother who was an agricultural grad revisited his old haunts and asked Hal how the dining room was going. Hal said he was looking for a cheap source of good meat. The grad said: "Well, I'm butchering some Aberdeen Angus, and I'll let you have one for fifty dollars." "Sold," said Hal, for this was a fabulously low price. About three weeks later the grad appeared with his beautiful steer, wholesale dressed, and unloaded him in the kitchen. He had with him about a dozen other old grads who had come along to see what Goulden would do with the carcass. Hal had provided himself with the necessary tools and had drafted a couple of husky freshmen to help wrestle the sides onto the large table, and he proceeded to cut up the beef and store it in the large refrigerated room which fortunately was a part of the old mansion housing the fraternity. The alumni stood around open mouthed, unaware that Hal's grandfather had taught him how to cut up a side of beef. Hal can still make your mouth water with his detailed and loving description of a juicy steak.

In addition to his fraternity jobs, Hal worked at various odd jobs to help finance his education. As a freshman, he tended the furnace of a retail store in New Brunswick, going there early in the morning to warm up the place. As he walked back toward the college, he used to pass a young lady on her way to the railroad station, a young lady who somehow attracted Hal's admiring attention, but he couldn't think of any means of striking up an acquaintance. Not until he was a senior did he actually meet this young lady, Mary Elizabeth Williams, who three years later became Mrs. Goulden.

Hal hung up an enviable scholarship record in chemical and biological sciences at Rutgers, graduating in 1923. Soon he joined E. R. Squibb & Sons, where he had the good fortune to work with a thorough-going

scientist, Lloyd K. Riggs. With Dr. Riggs, Hal worked on anesthesia, and soon he delivered his first technical paper, before the Biological Chemical division of the American Chemical Society in Baltimore in 1925. Hal's discourse was on the anesthetic effects of propylene, and he was complimented on it by a pioneer of American physiological chemistry, A. P. Matthews. Soon after, at the Thirteenth International Physiological Congress at Boston, Hal had the pleasure of meeting such other historic figures as T. C. Koch, Shiro Tashiro, and E. C. Kendall, and he will never forget his good fortune in meeting and chatting with the famous Pavlov, after which the great Russian physiologist presented him with an autographed photo of himself.

At Squibb's, Hal also studied the auto-oxidation of ether and developed methods for determining peroxides, dissolved oxygen, and aldehyde in ether which formed the basis of valuable patents. Hal left Squibb's to become director of White Laboratories, where he studied the effects of vitamins A and D on rats. Here he showed his ingenuity by developing methods for measuring vitamin deficiencies and for photographic recording of rickets. An early rapport was established with F.D.A. scientists when Dr. E. M. Nelson visited White Laboratories and asked Hal to write a letter substantiating the advantages of air-conditioned animal rooms. In this period, Hal obtained valuable experience as part-time instructor in biological sciences at Rutgers University College of Pharmacy in Newark. From White, he went to the Mennen Company as chief chemist, where he straightened out many formulas that had been causing production problems. Hal then became manager of the Jacqueline Cochran cosmetic firm, where he developed a full line of high quality treatment cosmetics and became familiar with all phases of the cosmetics business. While at Cochran, he was chosen as a member of the Toilet Goods Association Board of Directors, and on June 1, 1942, he resigned from Cochran to accept the position of Scientific Director of T.G.A.

In his 22 years at T.G.A., Hal has made full use of his early training in hard work and thorough scientific methods to promote in the cosmetic industry an awareness of the need for good cosmetic chemists in developing products that are safe, efficacious, and elegant. The members of the S.C.C. have indeed been fortunate in having a man of Hal's scientific competence and persuasive powers in a position where he has the ear of almost every cosmetics firm executive. The cosmetic industry has been singularly blessed in having a man who commands the respect and trust of key F.D.A. scientists and who can smooth the path

Mr. Robert Kramer (l.), President of the Society, presenting Medal to Mr. Harold D. Goulden (r.) at the 1964 Medal Award Dinner

to agreement on technical requirements for cosmetic materials and products.

Many of Hal's efforts on behalf of chemists and the cosmetic industry have, of course, been confidential and may never be recorded. One of his better known achievements has been the issuance of specifications for over 100 cosmetic materials. These T.G.A. Standards have become the industry's guide in purchasing ingredients that are pure, safe, and reliable. Each standard is the result of considerable cooperative effort of suppliers, users, and several cosmetic laboratories in developing, assembling, and agreeing upon the criteria to be used. Hal has organized this effort and has thus created a lasting monument that will long be used throughout the industry.

Everyone here knows of the crisis precipated by the recent F.D.A. drive on colors and other cosmetic ingredients. Hal's level-headed and expert services have been invaluable in this situation. His reputation at F.D.A. has won there the acceptance and approval of many reports and data that might have been refused if less ably presented. He has negotiated the approval of the test procedures now being used to determine the safety of cosmetic colors. He has organized the effort to gain acceptance of 44 non-coal tar color additives. He directed the adoption of new specifications for the halogenated fluoresceins, obtaining from F.D.A. many concessions favorable to the industry. Hal's ser-

vices in reviewing labels and advertising matter have been much appreciated by T.G.A. members.

Hal formed the Scientific Section of T.G.A., the first scientific group devoted solely to consideration of cosmetic problems. He also did everything he could to make possible the foundation of the S.C.C., and his efforts were a factor in the subsequent success of this Society. He has consistently sought cooperation between T.G.A. and S.C.C. for their mutual benefit.

The Handbook of Cosmetic Materials, by Greenberg & Lester, much utilized by cosmetic chemists, was published as a result of very extensive organizing and expediting efforts on the part of Hal Goulden. He wrote the sections on manufacture for the six booklets on cosmetics distributed by T.G.A. to many thousands of U. S. schools. These booklets have introduced countless youths to our industry and its products.

Hal has continuously preached research, research, and more research to industry executives. In innumerable cases he has pointed out the need for better laboratory facilities. He has shown management the need for competent chemists and the reasons for rewarding their efforts. He has a strong belief in a great future for the cosmetic industry, firmly based on scientific effort. This belief has been contagious and has been a remarkable and rare contribution to the art and science of cosmetics.

For all these reasons, I am most happy in leading the Society of Cosmetic Chemists in its recognition of Harold DeWitt Goulden as a worthy recipient of the Society's Medal.

Of Concern to the Cosmetic Chemist

H. D. Goulden*

You will agree, I am sure, that science has played an increasingly important role in the development of the cosmetic industry. The scientific method has largely replaced the empiricism of the past. Science has become so important that management of the larger companies find it convenient, if not essential, to "house" the company's chief scientist in their executive offices, where he is readily available for consultation. I would like to discuss a few matters that are of concern to the cosmetic scientist.

There seems to be very little doubt that new cosmetic legislation will be enacted. The question is merely—when? One cannot forecast what this legislation may be, but recently proposed legislation makes certain trends apparent. Such legislation is so interwoven with science that the best interests of the industry will be served if all proposed legislation is carefully considered by the scientist. Let me illustrate by example:

Recently proposed legislation, among other things, made it quite clear that a New Cosmetic Application would be required before a new cosmetic may be marketed, and such an application must contain a full list of the articles used as components of the new cosmetic and must contain a full statement of the composition of the cosmetic. It is not unreasonable to expect that some did not particularly object to the proposal. Most know what ingredients they are using to make a particular cosmetic; therefore, they know its composition. But do they? Let us study this in greater detail.

A simple lipstick formula was selected, and the chemical constituents in each of the ten ingredients, where known, were listed. Such a simple formula actually contained over 120 individual known chemicals and many unknowns. A perfumer friend supplied a simple perfume formula. Similarly, the components of each ingredient were listed where known. This raised the grand total to more than 250 and an undetermined number of unknown constituents. Can one forecast what will happen when such a mixture is processed into a lipstick? It is apparent that a

* The Toilet Goods Association, 1270 Avenue of the Americas, New York, N. Y. 10020

meaningful full statement of the composition of a cosmetic can only rarely be made, for the addition of perfume to the cosmetic generally adds a complex of many known and many unknown chemicals, making a full statement of composition well nigh impossible. This example has been cited to point out to the reviewing scientist that proposed legislation must be carefully, adequately and completely scrutinized.

A New Cosmetic Application, according to proposed legislation, would call for a complete description of the manufacturing process. This would include the kind and quality of ingredients used; a detailed description of the manufacturing process, including the packaging and labeling; details of the control procedures employed to assure that the ingredients meet specifications, that the manufacturing process is adequately controlled, that procedures are employed to prevent mislabeling of the product, and finally, that the finished product is subjected to adequate control procedures. Provision should be made so that minor changes in manufacturing, packaging and control procedures would not necessitate amending the petition. It certainly would be particularly burdensome if every time one made a change in processing, control methods or labeling, he would have to wait for an amended petition to be approved.

As proposed, a New Cosmetic Application would require the submission of data establishing the safety of the cosmetic, when used as directed or in the customary or usual manner. Certainly the cosmetic chemist developing a new product wants to know all about the physical, chemical and toxicological properties of the various ingredients he intends to use in formulating this new cosmetic. He knows that the finished product must be subjected to safety evaluation. It is, of course, a fallacy that one can make a list of hundreds of approved cosmetic ingredients and assume that any and all combinations of those ingredients will result in a safe product. The safety of a new formulation can only be assured by evaluating the product.

This will undoubtedly result in pharmacological evaluation of the product on animals, followed by clinical evaluation on man. The tests to be employed will be governed to a large extent by the nature of the product and its intended use. The final test, in my opinion, should be carefully planned sales in a very limited geographical area.

May I say a few words on the methodology of safety evaluation. As you know, I am supervising a pharmacological evaluation program covering some 25 certified colors and which has to date, cost about half a million dollars. Four species are involved: mice, rats, rabbits and

dogs. A detailed discussion of the methodology cannot be gone into here, but suffice it to say research should be undertaken in an effort to develop new methods that are shorter, more meaningful, and less costly. Methods that will permit us to forecast with much greater accuracy the effect that may be expected in man, not excepting carcinogenesis. We need better methods for determining the effects of materials topically applied to the human skin. We need more cutaneous toxicity conferences like that held last October in Washington, D. C., and more research that makes such conferences possible.

Before leaving a discussion of safety evaluation, I would like to point out a factor which is sometimes overlooked in assessing the "in use hazard." I refer to exposure. Exposure data are very significant for, if exposure to the substance under consideration is minimal, then the effect is minimal.

In order to determine the exposure of the consumer to trace materials in cosmetics, it is necessary to determine the per diem use of several types of cosmetics. The experimental method may be summarized as follows: Weighed packages of the cosmetic are given to the testers with instructions to use it in their customary manner for one week. The loss in weight is determined and is regarded as having been applied to the person of the user during the test period. This is actually loss from the container and disregards spillage, etc. *Per diem* use so determined may be regarded as maximum. In these studies the individuals chosen were normal users of the cosmetics to be tested, and they were supplied with the shades they were currently using.

We were interested only in maximum exposure; therefore, we took the maximum *per diem* use and not average use. For example: of the 222 women who participated in the lipstick study, we considered as the maximum *per diem* use the one person who used 73 mg. of lipstick *per diem*. We assumed that the lipstick contained 12.97% pure dye (about 1.5 times the average). We also assumed that she ate all she applied to her lips. It may be calculated that about 6 parts per million of her daily diet would be color.

We have found exposure data extremely useful in evaluating the hazard that may arise from the use of cosmetics. I will not go into the details here, but perhaps a few examples are in order. Let us suppose there is under consideration a limit of one part per million of mercury in color additives. We are able to show that in the case of a lipstick containing 43% color additives about 0.015 mg. of mercury would be ingested per *year*, and that in the case of a dusting powder which we will

consider to be 100% color additive about 1.5 mg. would be externally applied in a *year*. Even without considering all the "built-in" safety factors already mentioned, it would seem that any hazard is certainly minimal.

Previously, I have pointed out that research should be initiated to develop new methods for the safety evaluation of cosmetics. May I also make a plea for other industry research? It is to be hoped that in the near future some current or new organization will initiate a cosmetic research foundation that will be concerned with problems of industry-wide interest.

In this brief dissertation I have not detailed the role of science in the cosmetic industry. I have chosen to present some matters which are of particular concern to the cosmetic chemist.

To My Colleagues in the Society:

My sincere appreciation of this honor conferred upon me. To them, may I say that the opportunity for the cosmetic chemist is still unlimited; so much is yet to be done.

Thank you.

Left to right: Richard F. Sommers, Secretary; Harold Jackson, Chairman; Benjamin Kapp, Treasurer

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Chairman-Elect	Dr. Joseph Michaelson
Secretary	Richard F. Sommers
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Left to right (seated): James G. Atherton, Chairman; and Morris J. Root, Chairman-Elect. *(Standing):* Chester F. Moculeski, Secretary; and David A. Krochock, Treasurer

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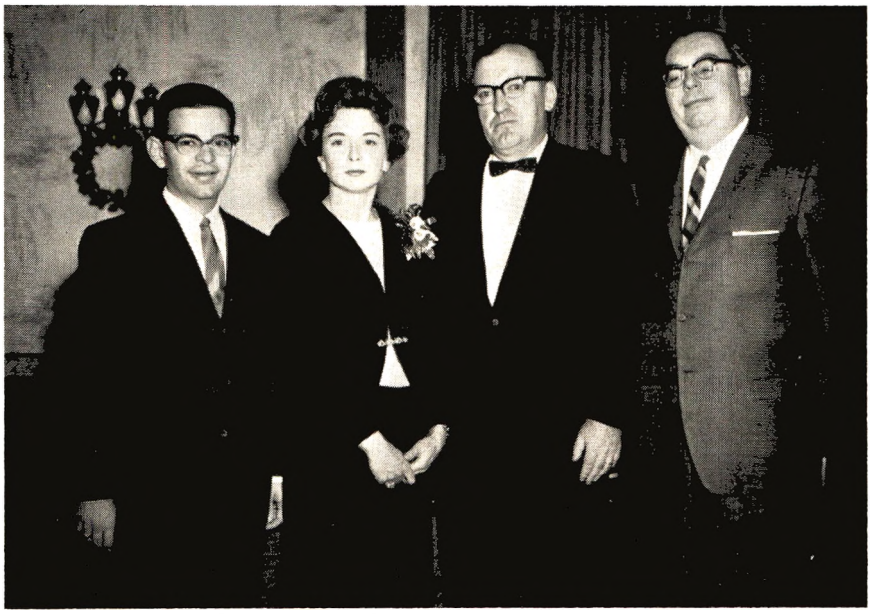
Policy and By-Laws	Dr. Hyman Henkin
Ladies' Night	Barton R. Owells
Special Awards Committee	Marshal Sorkin
Nominating	William D. Ackley



NEW ENGLAND CHAPTER OFFICERS

Left to right: Myron Slotsky, Treasurer; Sue Collins, Secretary; Edward Murphy, Chairman; James Dugan, Chairman-Elect

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Secretary	Mrs. Sue Collins
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Legislation	Dr. Robert Schuler
Inter-Professional Relations	Dr. Robert Swaine
Special Events	Hart Harris
News Letter	David Groves
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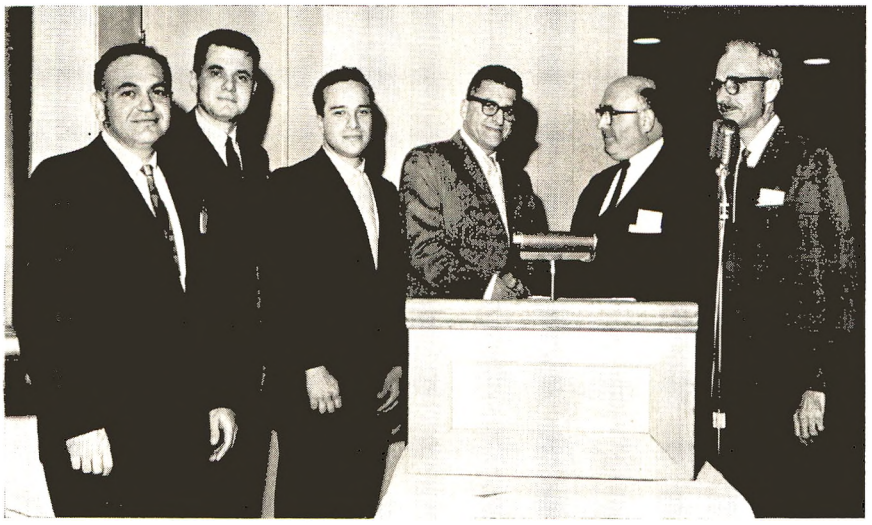

NEW YORK CHAPTER OFFICERS

Left to right: Mr. Stanley Brechner, Treasurer; Mr. George Fioto, Secretary; Mr. Mitchell Schlossman, Chairman-Elect; Mr. Charles Fox, Incoming Chairman; Mr. Henry Maso, 1964 Chairman. Mr. Robert Kramer (*far right*), 1964 President of the Society installed the incoming officers during the November 1964 chapter meeting.

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Chairman-Elect	Mitchell L. Schlossman
Secretary	George A. Fioto
Treasurer	Stanley Brechner

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House	J. Elmer Wolke
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Newsletter	Shirley A. DeRagon
Chapter Awards	Herbert Edelstein
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Ex-Officio	Henry Maso

New York Chapter Program

January 6, 1965	Hotel Shelbourne, New York, New York Dr. M. Shelanski, Industrial Biology Research and Testing Laboratories—"Skin Sensitization."
February 3, 1965	Hotel Shelbourne, New York, New York Mr. J. A. Peirano, Standard Color Chemical Company—"Nail Lacquer Formulation and Testing."
March 10, 1965	Hotel Shelbourne, New York, New York Dr. I. M. Sarasohn, E. I. DuPont de Nemours & Company—"Application of Differential Thermal Analysis to Cosmetics and Cosmetic Materials."
April 7, 1965	Robin Hood Inn, Clifton, New Jersey Mr. R. Thomas, Bristol-Myers Company—"Functions of a Cosmetic Packaging Laboratory."

Left to right: Dr. W. Coffey; Mr. and Mrs. Laden who accepted the award in the name of their son Dr. K. Laden; Dr. P. Finkelstein; and Mr. R. Kramer, President of the Society

I.F.F. Award 1963

The International Flavors and Fragrances Award was presented by Society President Kramer at the luncheon during the December, 1964, Annual Scientific Meeting. This award is given for the best paper published in the 1963 issues of the JOURNAL OF THE SOCIETY OF COSMETIC CHEMISTS and carries with it a stipend of $1,000. The I.F.F. Award will again be made in coming years.

J. Soc. Cosmetic Chemists, 16, 79–83(1965)

A Simple U.V. Absorptimeter for the Estimation of Certain Nonionic Emulsifiers and Other Aromatic Compounds

D. E. HERRING*

Presented before the Third Congress of the I.F.S.C.C., June 21–26, 1964 New York City

Synopsis—The construction and circuitry of an inexpensive U.V. absorptimeter are described. It is shown that this simple instrument is useful for the estimation and detection of emulsifiers and other compounds showing U.V. absorption.

Introduction

The use of U.V. absorption as an analytical technique is well known, and many excellent commercial U.V. spectrophotometers are available. These instruments (mainly research tools) are expensive and thus not particularly suited for routine laboratory work. The instrument described is a simple U.V. absorptimeter based on a low pressure mercury lamp† and was built for about £30. A low-pressure mercury lamp has a very intense emission at 254 mμ, and at this wavelength most aromatic compounds absorb strongly.

The basic instrument is shown in Fig. 1. The lamp is very close to the cell carrier, and immediately behind the cell are the OX7 filter‡

* E. R. Howard Ltd., Stowmarket, Suffolk, England.

† Low pressure mercury lamp—2 w., U shaped tube available from Engelhard Industries, Hanovia Lamps Division, Slough, Bucks, England.

‡ Chance filters OX1 and OX7 are manufactured by Pilkington Brothers Ltd., Chance-Pilkington Optical Works, Glascoed Rd., St. Asaph, Flintshire, Gt. Britain. These filters are available in cut pieces (4 × 2 in. or 6 × 2 in.) from Engelhard Industries, Hanovia Lamps Division, Slough, Bucks, England.

and selenium type photo cell.§ On the 254 mμ line the selenium cell gives sufficient power to operate a 0–10 micro-ammeter§, which is for convenience calibrated inversely logarithmically to read directly in optical density. The meter can be shunted either by a potentiometer or by a potentiometer placed in series in order to get a zero reading on a blank.

The original instrument was devised for the estimation of a nonylphenol ethylene oxide derivative (M.W. ≈ 600). It was found that this compound gave an extinction value of about 200 and that optical density was proportional to concentration from 0–0.07%, with a slight curve to 0.10%. It was anticipated that Beer's Law could apply only over a

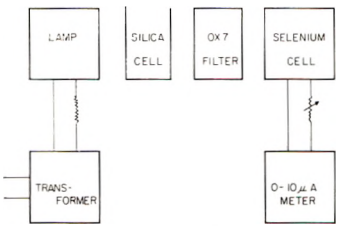

Figure 1. Low cost U.V. absorptimeter

very limited range. The main reasons for these errors were: (1) micelle formation; (2) non-linearity of output from the selenium cell feeding into a fairly high resistance (the meter has a resistance of 2000 ohms plus the series resistor); and (3) wide band width and stray light.

Figure 2 shows calibration curves for a number of other compounds as well as nonylphenol ethylene oxide condensates. These curves show that aromatic anionic compounds, such as sodium dodecylbenzene sulfonates, have very high extinction values (≈ 700) which would cause serious interference in any determination of nonionic material. The technique used to overcome this is to pass the sample through a small mixed-bed ion exchange column; this eliminates interference due to salts, anionic detergents, and cationic surface active agents. By the use of mixed-bed resin, a larger concentration of ionic salts can be removed in a small column than would be possible by the same weight of resin in two separate beds; the resin must, however, be discarded after use.

The procedure for the estimation of a nonylphenol ethylene oxide condensate in presence of sodium dodecylbenzene sulfonate is described below.

§ Selenium photocell-rectangular 22 × 40 mm.; microammeter, 0–10 μA calibrated in transmission and absorption; both available from Evans Electroselenium Ltd., St. Andrews Works, Halstead, Essex.

Experimental

Reagents

Strong acid cationic exchange resin (H^+ form)
Strong base anionic exchange resin (OH^- form)

Procedure

The test solution should contain 0.02 to 0.10% of the nonionic and not more than 0.10% of sodium dodecylbenzene sulfonate or other ionic impurity. Ten grams of anionic resin and 10 g. of cationic resin are mixed, poured into a 2 cm. chromagraphic column, washed with water,

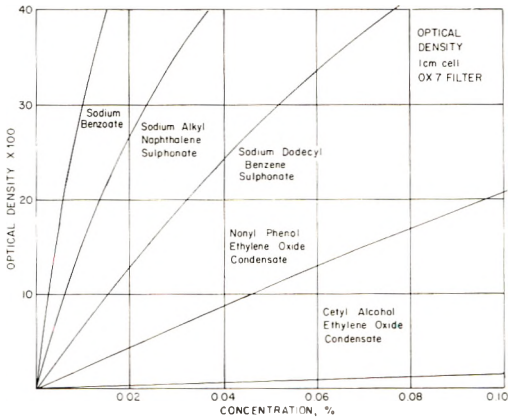

Figure 2. Typical calibration curves

and drained. The solution under test is passed slowly through the bed. The first 40 ml. are discarded, but the next 5 ml. are used to read the U.V. absorption. The concentration is determined by references to a calibration curve.

Results

Nonylphenol, octylphenol, isobutylcresol ethylene oxide condensates all give an extinction coefficient of about 200, depending on molecular weight. Saturated alcohol ethylene oxide derivatives give an extinction coefficient of about five, possibly due to impurities. Unsaturated alcohol ethylene oxide derivatives give values from 50–150, and condensation products containing oleic acid also give values of this order of magnitude.

The determination can be carried out in methyl alcohol as the solvent if the emulsifier is insoluble in water.

Since this is a divergent beam instrument, the alignment of the cells can be extremely important. Equally important are reflections on the side of the cell. It was found, however, that if the cell could be located within 0.5 mm. these errors rarely amounted to more than 0.5% of the total reading. The unit is subject to voltage variation, and as was expected this can cause errors up to 1%. This error cannot be avoided, and the only way to ensure that it is not serious is to check the zero on a blank before and after taking readings.

A major source of error can be dirty cells, due mainly to absorption of surface-active agents on the silica cell. It is essential to clean the cells

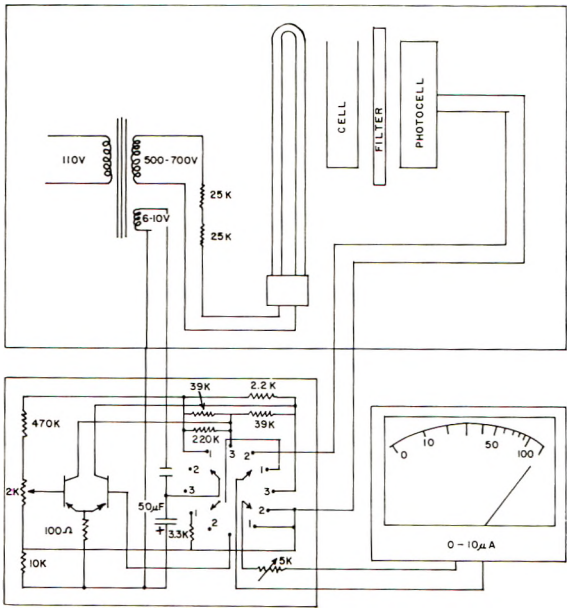

Figure 3. U.V. absorptimeter with built-in amplifier (components: Mullard OC70 or similar A.F. pnp type transistor; silicon 50V 100MA rectifier)

continually with chromic-sulfuric acid. The chief disadvantage of the 254 mμ band is that it is non-selective, and a vast range of compounds interfere and must be removed as described above. A low-pressure mercury lamp has about 5% emission in the 315 to 360 mμ range, and attempts were made to utilize this band for estimation of certain compounds.

With a Chance OX1 (Woods glass) filter and glass cells, about 1 micro-amp. only is obtained from the cell, and either this must be con-

nected to an external galvanometer or fed through some kind of amplifier. Both techniques have been used. The unit was used for some time with an external galvanometer, but this was rather clumsy; to overcome this, a small transistor amplifier was built into the unit. The details are shown in Fig. 3.

The instrument has, in fact, three ranges:

1. The meter is shunted so that it is possible to use all the output from the mercury lamp (except the 254 mμ band) with a glass filter, thus giving a series of bands from 300–560 mμ.

2. The photocell is connected directly to the meter, and thus this position is primarily intended for use with a Chance OX7 filter and silica cells. This gives the specific 254 mμ band referred to earlier.

3. The photocell is connected via a x10 transistor amplifier to the meter and intended for use with a Chance OX1 filter and glass cells. This gives a series of bands from 310–360 mμ. In this band, the choice of solvent is not quite so critical, nor is the cleanliness of the cells. A wide range of materials (particularly natural compounds) obeys Beer's Law over a limited concentration. Thus, resinous compounds, many essential oils and perfumes, and optical whiteners give useful absorption in this range. It is essential to use glass cells in this range since fluorescence can cause serious errors.

Summary

A U.V. absorptimeter was built because no inexpensive instrument could be obtained commercially to do the required job. Whether similar instruments are available in America or in Eastern Europe is not known. It has been shown that this instrument has utility for the routine determination of compounds showing absorption in the U.V. range.

(Received June 24, 1964)

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Florance, Richard K., 125 Old Wood Lane, Boonton Township, N. J. 07005
Garceau, Bertram J., 1 Cliffside Dr., Lincoln, R. I. 02865
Greif, Martin, 1520 Archer Rd., Bronx, N. Y. 10462
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Khoudary, Harry Z., 7416 Sixth Ave., Brooklyn, N. Y. 11209
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J. Soc. Cosmetic Chemists, 16, 85–90(1965)

The Role of Government in the Field of Cosmetics

VINCENT A. KLEINFELD*

Presented before the Third Congress of the I.F.S.C.C., June 21–26, 1964
New York City

Synopsis—The wide distribution and vital importance of cosmetics to women raises some serious problems in the marketing of cosmetics. A limited number of persons may experience an unforeseeable reaction to virtually every cosmetic, and it is not feasible to specify a rigid series of tests which will disclose the possible incidence of injury caused by all cosmetics. Instead each new preparation must be subjected to tests designed by experts.

The majority of cosmetic manufacturers conduct careful scientific tests before their products are marketed. However, some have not observed the necessary precautions, seek to obtain an unfair competitive advantage, and have caused the enactment of regulatory legislation. In the 1938 Federal Food, Drug and Cosmetic Act, Congress set forth the circumstances under which a cosmetic shall be deemed adulterated and misbranded, and severe penalties for violations were provided.

Notwithstanding this, injuries occurred, and, in view of the public demand for greater protection, new legislation appears inevitable. The important question is how far one wishes to go in affording additional protection to the consumer. This depends, in large part, on one's theory of government. A statute can be devised which will place the industry in a strait jacket so that most old cosmetics will be regulated out of existence and virtually no new ones will appear. It would appear advisable, instead, to provide for the pretesting of new cosmetics or of their ingredients before the cosmetics are placed on the market. More stringent legislation may adversely affect the public as well as the industry.

There is no doubt that serious problems are always involved in the marketing of cosmetic preparations. The normal human skin may be injured in several ways as a result of cosmetic application, and there is probably no ingredient which can be used with impunity by every human being. In the case of virtually every cosmetic, some limited number of persons may experience an unforeseeable reaction, although all others may suffer no ill effects.

* Bernstein, Kleinfeld and Alpen, Washington, D. C.

Unfortunately, it is not feasible to specify a rigid series of tests, satisfactory for all cosmetics, which will be adequate to disclose the possible incidence of local contact dermatitis, or loss of hair, or eye injury. Each newly introduced preparation must be subjected to specific tests designed by experts, which take into consideration the types of ingredients, the intended manner of use of the product, and its estimated potentialities for producing particular kinds of irritation.

This is essentially the procedure employed by the responsible cosmetic manufacturers who comprise the bulk of the industry. Thus, former President Roosevelt pointed out to the Congress of the United States, when the bills leading to the enactment of the Federal Food, Drug and Cosmetic Act of 1938 were under consideration, that the great majority of those engaged in the food, drug, and cosmetic industries do not need regulation—that "they observe the spirit as well as the letter of existing law."

The attempts of organized society to regulate the commerce in foods and drugs are by no means a recent development. Early Greece and Rome had wine inspectors to guard against adulteration. Sanitary regulations concerning food are found in the Rabbinical laws. During the time of William the Conqueror, brewers were heavily fined for adulterating their product and were drawn around in carts to receive the jibes and execrations of an outraged citizenry. During the eleventh century, regulations were enforced in several European cities forbidding the adulteration of wine and beer. In 1202, the "Assize of Bread" was passed in England, and in 1266 a law was enacted forbidding the sale of unwholesome wine and meat. The Magna Carta contained a provision dealing with weights and measures. A pharmacopeia was published in England by the College of Physicians as far back as 1613.

It was the development of analytical chemistry, with the creation of methods for detecting adulterants, which stimulated an increased interest in legislation directed against sophistication. An indication of the fact that the adulteration or misbranding of cosmetics was not taken too seriously was the fact that, when the first national Food and Drugs Act was enacted by the United States in 1906, there was no attempt to include cosmetics in the protection offered to the consuming public. There were a number of incidents, however, some quite serious in nature, which soon revealed that protection against abuses in the distribution of cosmetics was necessary. For example, a product named "Lash Lure" caused irreversible blindness to a few women who were particularly susceptible to the *p*-phenylenediamine which it contained. A

depilatory, "Koremlu," caused thallium poisoning in some women, resulting in symptoms such as abdominal pain, nausea, loss of hair, and blindness. A product called "Inecto Rapid Notox" also caused serious injuries because of the *p*-toluylenediamine in its formula. Thus, when the Federal Food, Drug and Cosmetic Act of 1938 was enacted, Congress set forth the specific circumstances under which a cosmetic shall be deemed to be adulterated or misbranded, and severe penalties were provided for those distributors or manufacturers who marketed products which could cause injury or whose labeling made false or misleading claims.

The injuries resulting from the use of improperly tested cosmetics were primarily responsible for the inclusion of cosmetics in the law which prior to 1938 had concerned itself solely with the marketing of foods and drugs. There is no question but that the regulation of cosmetics in the 1938 Federal Food, Drug and Cosmetic Act greatly decreased the incidence of harm caused by cosmetics. But, despite the fact that there have been very few serious injuries since the passage of the 1938 statute, instances involving some injury to some consumers have occurred. For example, there was an outbreak of dermatitis as the result of the substitution by a manufacturer of synthetic resin for shellac in the manufacture of a hair lacquer very popular at the time. A number of years ago, two hair shampoos were marketed which, when inadvertently introduced into the eyes by users while shampooing their hair, produced opacity of the cornea which impaired vision for a period of time. There have been other instances of harm—from hair dyes, hair straighteners, depilatories, deodorants, and other cosmetics. Among the injuries resulting from the use of such cosmetics were skin eruptions, itching, and brittleness and temporary loss of hair.

The fact that the 1938 Federal Food, Drug and Cosmetic Act specifically provided that new drugs must be demonstrated to be safe for their intended use before they are marketed certainly did not prevent a number of side effects, some of them quite serious, as well as deaths from new drugs which had obtained prior governmental clearance. This is not to say that regulation is not needed or that the new drug provisions of the statute do not serve an extremely useful purpose. The point is that it is virtually impossible to have an absolute assurance that some few persons may not suffer some side effects, occasioned by the use of a particular drug or cosmetic, unless such drastic legislation is enacted. Thus legislation would probably result in a collapse of the drug and cosmetic

industries, or at least the removal from our economy of large numbers of safe and useful products.

The fact remains, nevertheless, that literally hundreds of chemicals are utilized in cosmetics and that the number of chemicals entering the cosmetic market of the world increases each year. Many millions of men, women and children use cosmetics every day in one form or another. Since 1938, the percentage of injuries caused by the many millions of units of cosmetics marketed is quite small. As pointed out, nevertheless, injuries have occurred. There is a strong popular demand for increased consumer protection. These considerations appear to make it inevitable that the State will enter into the cosmetic picture in a stronger fashion than before. But what kind of legislation do we need, and how much power do we wish to give to the State because of these factors?

The important question at this time is how far we wish to go in affording additional protection to the consumer. This depends in large part on one's theory of government. As indicated, one can devise a statute which will vest such authority in the State and require such testing and safeguards that most old cosmetics will be regulated out of existence, and virtually no new ones will appear. In addition, one can cause such increase in the cost of cosmetics as to create a serious financial burden upon many millions of consumers. We can over-legislate and over-regulate so that the small businessman who may be considered to be a bulwark of the economy of many nations is driven from the market place.

Taking everything into consideration, it would seem to be advisable to provide, as far as the United States is concerned, for approval of the safety of a new cosmetic by the Food and Drug Administration before it is permitted to enter the channels of commerce. But it would appear that, particularly in this area, there is no necessity for a complicated and burdensome statute which, for example, provides that investigations must be conducted which will "include adequate tests by all methods reasonably applicable to show whether or not" the cosmetic is not only safe for its intended use but for "other reasonably foreseeable uses." Again, is any vital purpose served (other than to create a greater labyrinth of governmental regulation) by declaring that a cosmetic will be deemed unsafe not only if its intended use, but also if "any reaonably foreseeable use," will or may result in ingestion and is found by the Government to be carcinogenic in some amount, to some strain or species of animal, under some circumstances, when applied in some manner, and

at some stage of development? And concerned as we all are with respect to cancer, is it realistic to provide, in addition, that a cosmetic shall be deemed unsafe not only if its intended use, but again if "any reasonably foreseeable use," will not result in ingestion, and "after tests which are appropriate for the evaluation of the safety of cosmetics for any such use, or after other relevant exposure of man or animal to such cosmetic" is found by the Government to induce cancer "in man or animal?" Is there any necessity for requiring a cosmetic manufacturer to demonstrate in advance, to the satisfaction of the Government, that his labeling is not false or misleading? What does that have to do with safety?

A bill introduced in Congress also provides that a cosmetic shall be deemed unsafe if its composition is such that it is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of cosmetics, as having been adequately shown, through scientific investigations, to be safe. . . ." The author certainly has no quarrel with a provision of this character, as far as it goes, or with the opinions of learned experts. But the provision completely ignores, in connection with cosmetics which may have been on the market for many years, what is in the author's view the most authoritative criterion—actual experience.

The problem presented by the scope of proposed social and economic legislation is frequently the same. There are always certain inevitable conditions encountered in the enactment of such legislation. There is the influence of that group which has a real concern for the public welfare but which possesses, in addition, interests which cause it to seek precautions against abuses in the administrative process. There is the element which, when any regulation is attempted, commences by declaring that it is for effective legislation and then seeks to emasculate it by a multitude of weakening amendments. There is a small, selfish element that is opposed to any regulation at all, no matter how essential it may be. And lastly there are the doctrinaire consumer groups, backed by the more sophisticated agencies concerned, who take the opportunity offered by a need for some remedial legislation to add unnecessary restraints and licensing provisions. These countering cross-pulls are always present, and all should be scrutinized.

In any event, if a strait jacket type of cosmetic legislation is to be enacted, is it not advisable to have a check on the particular reviewing governmental official by providing for a review by some committee of qualified scientists? As indicated, also, it would appear that those

cosmetics which have been on the market and have not caused injury, other than perhaps an occasional allergic reaction, should not be placed in the precise category of a "new cosmetic." Has not such a cosmetic been shown to be safe by the very fact that it has been used for an appreciable period of time without a real incidence of injury?

In addition, it is vital to comprehend the importance of semantics as far as the law of this country is involved. The Federal Food, Drug and Cosmetic Act of 1938 specifically defines "drug," "new drug," and "cosmetic." Frequently, a few words may convert a product which is essentially a "cosmetic" into a "drug" or "new drug." Thus, an article offered to provide a woman with a rich tan will be considered to be a cosmetic, the labeling of which need not declare the ingredients. The same product may be converted into a drug if it is marketed to afford relief from sunburn. A face cream is a cosmetic, but it may become a drug, in addition, if it is held out for the removal of wrinkles and crow's feet. A tooth powder will be a cosmetic if offered to keep teeth clean and breath fresh, but it may fall into the drug category if its labeling or advertising claims that it will prevent decay. I point out this factor to indicate that legislation in the United States, attempting to regulate more stringently the marketing of cosmetics, should take into account the fact that the definitions in existing law of "drug" and "new drug" are so comprehensive as to encompass (with the attendant strict controls presently in existence for these products) many articles which are fundamentally cosmetics but which employ active ingredients and make representations which are somewhat therapeutic in nature.

In summary, there appears to be a need for greater regulation in the area of cosmetics. In the United States, new food additives, new drugs, antibiotics, and colors must be shown to be safe before they are introduced into interstate commerce, and there is a strong demand for a similar requirement with respect to cosmetic preparations. In view of these considerations, it would seem inadvisable to resist the passage of reasonable legislation requiring that new cosmetics, or their ingredients, be demonstrated to be safe before they are marketed. Balancing all the pertinent policy considerations, however, the creation of unnecessary restrictions, even if they may seem at first glance to afford the consumer greater protection, would be ill advised.

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Public Safety and the Cosmetic Chemist—A European Review

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Presented before the Third Congress of the I.F.S.C.C. June 21–26, 1964, New York City

Synopsis—The cosmetic industry's position concerning legislation involving toilet preparations and cosmetics in European countries is reviewed. The proposals of the European Committee on Chronic Toxicity Hazards (Eurotox) are discussed, and the I.F.S.C.C. policy toward positive and negative lists of cosmetic ingredients is reviewed in the light of these considerations. Some salient features of legislation in various countries, which may affect the formulation and marketing of cosmetics, are pointed out in the appendices.

In all civilized countries there is a socially accepted concept that the public at large is to be protected from harm. The extent to which this social duty is spelled out in statute law, endorsed by regulation or confirmed by custom differs from country to country but all concerned with the manufacture of goods for sale or use by the public are affected by this accepted responsibility.

The background to this legislation is a correlation of experience—human or animal—with definable ingredients and sometimes concentrations. The reasons for these experiences are not of concern here, although a vast amount of research is carried out in order to relate physiological activities of toilet products, whether beneficial, harmful, or nil, to chemical properties. Instead the results of using products and in particular the avoidance of harmful results are of concern. Even as in the drug field, the net gain to the consumer is the real yardstick, and it is known that if the psychological misery of, for instance,

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unwanted facial hair is very great, a measure of risk, or pain, or trouble is readily acceptable in return for the benefit obtained by removing the source of the misery. This aspect cannot be ignored in relation to the more dramatically active products, but the measure of risk or pain must be known and understood by the consumer.

This argument would indicate that the best methods of control should be based on tests-in-use of the whole product and in a sense this is accepted in use of, for instance, the Draize rabbits-eye technique. With all the difficulties attached to biological experiments, this is preferred to listing and specifying maximum concentrations of all possible active detergents and their combinations. In practice, no matter how many positive and negative lists are produced, the conscientious manufacturer will continue to carry out animal tests for sensitization properties on the whole product.

Such tests of experience are, in the right hands, a valid protection for the consumer against primary irritation and sensitization. Indeed, primary irritation is not a danger in itself—it is a warning. Shampoos with local anesthetic action are dangerous because they do not irritate the eye and warn of possible damage. The public needs, however, to be protected against sensitization risks, and these are avoided by restriction of ingredients known to be troublesome and by the whole product testing already mentioned. Such restrictions can help to protect the public in general but cannot be expected to guard against exceptional idiosyncrasy.

It is the impossibility of the consumer guarding himself against long-term toxicity—essentially cancer or cumulative poisoning—and the difficulty of whole product testing that has given the greatest force to the spread of legislation relating to ingredients.

Legislative control of the cosmetic industry probably reaches its most explicit form in the U.S.A., and this provides the maximum number of research and development problems but perhaps consequently the minimum number of interpretation problems. In Western Europe generally the position is somewhat different, although currently tending to alter toward a more explicit control but probably not on the same lines as in the U.S.A.

In detail, however, the positions in European countries differ widely, and particulars are given in Appendices I–XIV. For a further statement on the U.K. position reference is made to a paper delivered by Brett to the 1963 Symposium on Toxicology held by the Society of Cosmetic Chemists of Great Britain (1). A law relating to toiletries

alone does not exist. The manufacturer of cosmetics in the U.K. is concerned with general legislation, dealing particularly with misrepresentation, poisonous substances, and curative claims, and, above all, the cover of Common Law. So far as ingredients go, the only control is either negative, i.e., prohibition, or in some instances, limitation.

In France there is no general legislation covering toilet preparations; somewhat similarly to the British procedure, there are a number of specific restrictions or limitations, particularly in relation to colors where there is in practice a permitted list. Germany and Denmark have laws referring to toiletries but only in general terms; the effective control is exercised by regulation. In Holland, Belgium and Italy specific laws are in course of preparation, and the substance of these is not yet available.

The existence of the European Common Market is an important factor in considering the future of European laws. The six, that is, Germany, France, Italy, Holland, Belgium and Luxembourg, have incorporated in the Treaty of Rome the provision that in due course certain areas of legislation will be harmonized, i.e., the laws of the countries will be brought into line with the main object of freeing trade within the Common Market. At a deliberate pace the legislative bodies of the Common Market are carrying this out, naturally beginning with those areas where all six countries have already comparable legislation. This does not yet include cosmetics, but shortly the position will arise where, with Holland and Italy both having near-completed legislation, harmonization will begin officially. The commission starts working on harmonization as soon as more than one country has its own legislation in certain areas.

Consider the problems of an international research and development department. Let us take a purely imaginary case. Assume that a new mouthwash was invented with a certain organic fluoride (call it FX). FX has the remarkable property of curing (or at least improving) ordinary male baldness, if you rinse your mouth with its diluted solution once a day. In Holland you will have no chance whatsoever of marketing it; a mouthwash is a toilet preparation, and fluorine compounds are forbidden in toilet preparations.

In the United Kingdom, not because of a law but because it is good scientific practice, it is necessary to convince the experts after years of testing on animals and human beings that the product is absolutely harmless. But the television authorities do not believe in the curative powers against baldness (only 100 bald volunteers were tested and at

least 1000 are required). Hence the company is not allowed to use television as an advertising medium, which means that the product will never get a profitable share of the market, and so the United Kingdom is out.

In France the product is considered to be a pharmaceutical as it has definite curative properties. So the company is allowed to sell it only via pharmacists, where there is no sale of mouthwashes; so France is out as well.

In Belgium the company decides not to use the story of hair recuperation. But "FX" is mentioned in the Belgian Pharmacopoeia, and this means the product can only be sold through pharmacists anyway. The rest of the story is analogous to the French situation; so Belgium is out.

In Germany the toxicologists take a very jaundiced view of the matter. The results of the U.K. tests are not extensive enough. At long last after years of experiments in Germany everybody there is convinced that the product is not carcinogenic, but then it is found that the lethal dose of "FX" is just under 1 g./kg. body weight. Only 0.004% of "FX" is used in the product, but this is of no avail; Germany is out. Austria follows Germany six months later.

Italy and Finland get very nervous once they hear the product has been forbidden in Germany. The daily papers bring staggering stories supplied by competitors about all the people killed by the mouthwash. Questions are being asked in Parliament. In two weeks time they will come to the irrevocable conclusion that Italy and Finland have to forbid the product.

Various other countries take a more liberal view. Norway, Sweden, Denmark and Switzerland are all willing to help, but as their scientists do not accept the work of foreign scientists the company is obliged to do all the testing over again in four different countries. Unfortunately in the meantime so much money has been lost that the company has to curtail operations of the new product.

The law, however, should reflect the public conscience and we should be inspired not indirectly but directly by public conscience. Cosmetic scientists and members of the public have been impressed by the ever-increasing requirement for proof of consumer safety, and proof of product performance in relation to advertising or similar claims. The need for maintaining and raising the standards for safety and proof of performance was widely appreciated in Europe, and not merely because of the lengthening shadow of the F.D.A. in the U.S.A. This

heightened public consciousness of the need for critical examination of consumer products, instanced by the widespread activities of Consumer Associations, was a reflection too of the social responsibility of the manufacturers and their own scientific conscience.

Like all matters of conscience this awareness was sharpened by enlightened self-interest. One cannot understand how many of the critics can imagine that businesses can be run on the basis of endeavoring to harm customers. Goodwill of companies, brands and products is much too valuable to put at risk.

This rise in consciousness led to the 6th Meeting of the European Committee on Chronic Toxicity Hazards, known familiarly as Eurotox, being devoted to cosmetics and toilet preparations. Eurotox is a non-official body of leading European toxicologists who find their personal and unofficial status beneficial to their unprejudiced consideration of matters of public safety. In fact, of course, many of the individual members of Eurotox are also acting in a more formal capacity on World Health Organization or F.A.O. Committees.

At this Symposium in 1961, Eurotox followed its usual practice and invited experts qualified in the field under examination. Many leading members of the European cosmetic chemists were present, as also were experts from the U.S.A. The recommendations of this meeting (2) have undoubtedly had considerable influence on subsequent moves in Europe. The particular general recommendation is as follows:

> "Control over the constituents of cosmetic and toilet preparations is one way in which the exposure to substances having delayed toxic effects could be reduced. The problem of control of these preparations is similar to that of food in general, but different in details.‡ In the field of food additives the principle of positive lists of suitable products is generally accepted. In cosmetic and toilet preparations the ingredients could be classified as suggested for the colors by Deutsche Forschungsgemeinschaft-Farbstoff Commission-Mitteilung 3§ as follows:
>
> "C—completely acceptable for use in any cosmetic including those that can be ingested (e.g., in lipstick or dental preparations).
>
> "C-Ext.—for external use only—not necessarily safe for ingestion.

‡ The evaluation of the toxic and carcinogenic hazards of food additives is considered in the 2nd and 5th reports of the Joint FAO/WHO Committee on Food Additives (1958 and 1961).

§ Second Edition 1959 (F. Steiner Verlag, Wiesbaden).

"C.W.R.—for use in washing and rinsing, or as a solvent or propellant, provided that the material has only transient application; not necessarily safe when ingested or remaining on the skin.

"Classification should depend on the nature of the preparation and, more especially, its usage. The substances in Class C which are completely acceptable should either be 'generally recognized as safe,' or have been approved after testing in at least two species of animal, for example, by feeding to rats over a period of two years and by skin application to mice for 80 weeks. Dogs may be useful for discovering toxic effects in short-term experiments but appear to be unsuitable animals for the skin testing of cosmetic ingredients, because dog skin is relatively impermeable. Substances in the categories C—Ext and C.W.R. may be controlled. Products known to be harmful under the conditions of use in cosmetics should not be allowed."

All law is a compromise between liberty and license, and the duty of scientists is to ascertain the facts so that there is no unnecessary restriction. The role of the cosmetic chemist has been interpreted by the I.F.S.C.C. in a Policy Document now in course of ratification by member societies. Action to date has inevitably taken some lead from the Eurotox recommendations, which are backed by a strong body of internationally recognized toxicologists, but their views have been tempered by advice and help from the trade associations. Since negotiations with regulatory bodies on behalf of the trade will be concerned with many factors of little scientific content but of considerable commercial importance, such negotiations will normally be carried out by the trade associations, who may nevertheless appoint scientists to handle many of the facets and have done so already in some countries. The job of the I.F.S.C.C., however, is to hang out the sign that scientific information is available on request. Scientific data have been prepared to be available for discussions on all possible proposals, and particular attention has been paid to the harmonization of Common Market legislation. Here we are faced with a toxicological suggestion of limited positive lists on the Eurotox lines, but positive lists suffer from three main difficulties.

The first is that of being fully comprehensive, which implies an amount of testing beyond reasonable possibility, avoided only by the G.R.A.S. approach, and, secondly, a possible lack of commercial security in that a unique ingredient may have to be declared for public inclusion. The third difficulty is that without efficient crystal balls anticipation of development is impracticable; therefore a facility for addition is es-

sential to avoid frustration, and this facility is found difficult to incorporate without affecting the intended safeguard.

Negative lists as often discussed have their own problems, much of the same nature in origin. Thus comprehensiveness would imply listing poisonous materials never likely to be used—are cyanides banned from toothpastes? Similarly, too swift a facility for addition could result in frustration from capricious conservatism.

Nevertheless on balance, negative lists present less difficulties if used rationally. By rational, in context, is meant treatment of cosmetics in general as if the class was a single material to be specified. The foreword describes the material in general and only likely deviations are controlled specifically. Thus consider mineral oil, liquid petrolatum, U.S.P.—there is, for example, no specified limit for halogenated hydrocarbons because these are not expected to be found in mineral oil by accident and would be of no advantage to anyone by intent.

All countries having "Poisons Laws" have in essence a form of negative list, but there is no reason for any unnecessary extension of such legislation, and we should not yield to or encourage controls inherently illogical. Such negative legislation as is required should be as rationally based as the impurities clauses in pharmacopeia specifications, permitting that which is necessary, inevitable and harmless and drawing the line at the harmful and deleterious.

Our colleagues in the food business assure us that safety is relative. Water can intoxicate, salt can kill, pepper can blind, oysters and strawberries can produce idiosyncratic reactions. Nevertheless, scientists must ensure that consumer products in normal use, even in modest misuse perhaps, will not cause harm to the population at large and that claims shall be reasonable and demonstrable. Legislation should reflect these views and assist the protection of the public from the careless and unscrupulous without frustrating the effective development of cosmetic and toilet preparations with improved consumer attributes.

(Received August 12, 1964)

References

(1) Brett, L. C. J., *J. Soc. Cosmetic Chemists*, **15**, 195 (1964).
(2) *J. Soc. Cosmetic Chemists*, **13**, 322 (1962).

Appendix I

Austrian Legislation

The dyestuffs for cosmetics are covered by regulations given in the "Farbenverordnung," which has been modified several times (e.g., 1.8.1963; 6.11.1963; 31.12.1963). A positive list of dyes is given for foods, which is taken as binding for dentifrices and mouthwashes as well. All other cosmetics which come in contact with mucous membrane are only allowed to contain dyes on a given positive list.

Appendix II

Belgian Legislation

There is currently no specific law relating to toilet preparations, but a proposal has been made for blanket legislation requiring positive clearance of ingredients.

The draft of the new Belgian food law also contains provisions on toilet preparations.

Appendix III

Danish Legislation

Legislation prohibits certain heavy metals and organic solvents and also paraphenylene diamine. In hair dyes paratoluylene diamine is admitted up to 4%. Chloroform is, however, permitted in dentifrices up to 4%.

The use of certain fluorine compounds is prohibited, but as far as toothpaste is concerned dispensation is possible.

Natural hormones are allowed up to 1 g. estrone in 100 kg.

The position is generally similar to that in the U.K. in that law 119 of 3.5.61 is a general poisons law.

Appendix IV

French Legislation

There is no general law covering toilet preparations as a class, but restrictions arise from the sections of the law on pharmaceutical products dealing with poisonous substances.

There is a specific section on hair dyes which prohibits the use of paraphenylene diamine but permits paratoluylene diamine with certain

labeling restrictions and requiring a preliminary test. Thioglycolic acid and its derivatives are not permitted for use in products for retail sale, and there is a concentration limitation (8%) even when used by hairdressers. Other substances prohibited include hydroquinone, lead salts, and carbon tetrachloride.

Dyestuffs are restricted by custom to a positive list originally prepared by the Syndicat Nationale de la Parfumerie.

Products with curative properties are, in general, restricted to sale through pharmacies, as are products containing specified poisons and drugs.

Appendix v

Finnish Legislation

According to the "Statute relative to Foodstuffs" (Promulgated in Helsinki November 21, 1953) toilet preparations belong to "general utensils and consumer supplies." As such, these products shall not be prepared in a manner so that they might cause poisoning or other illness when being used for their conventional purpose.

Moreover, what has been enacted in the Law Relative to Foodstuffs (3.7.1941/526) regarding foodstuffs is in force equivalently with respect to stimulants and those general utensils and consumer supplies which, because of either their method of manufacture or their ingredients, can be injurious to health.

As yet there is no specific law barring the use of certain ingredients.

Appendix vi

German Legislation

There is no specific law covering toilet preparations, but they are covered by the laws dealing with general consumer goods and medicaments.

The positive lists prepared by "Deutsche Forschungsgemeinschaft" for dyestuffs and colorants (Mitteilung 3) are taken as binding. Dental preparations are treated as foodstuffs and can only contain food colors.

There is a specific law barring the use of paraphenylene diamine, but paratoluylene diamine is permitted. There is no positive list of colors for use in hair dyes which are excluded from the regulation.

Products with curative properties are in general restricted to sale through pharmacies.

The draft of an act on restrictions for advertising drugs, toilet preparations and dietetic food has been submitted.

Appendix vii

Hungarian Legislation

The regulation Nr. 1/1963/II.20/Élm.M. covers the dyestuffs used in cosmetics with the exception of hair dyes and dyes for eyelashes. This new regulation is based on positive lists after the example of the analogous American, English and German lists. The number of the permitted dyes is increased from 88 to 95.

Appendix viii

Italian Legislation

A new law was published on March 7, 1963, covering food additives, and a cosmetic law is being drafted.

Appendix ix

Netherlands Legislation

A draft toilet preparations order was published on July 5, 1963, which defines toilet preparations and lays down certain general controls. Substances excluded include named heavy metals and poisonous non-metals, aniline, antibiotics, benzene, cortisone, estrogens and β-naphthylamine. Limitations are placed on pyrogallol, β-naphthol, formaldehyde and on pH and flash-points.

A positive list of dyes is given for products in class "C." Products for external application may contain phenylmercurials as preservatives up to 0.001%. Limitations are placed on thioglycolates.

Appendix x

Norwegian Legislation

Cosmetic products are mentioned in §16 of the Norwegian food and drugs act ("Alminnelige forskrifter om tilvirkning og omsetning av naeringsmidler M.V.").

With some exceptions it is forbidden that they contain the following elements and their compounds: Sb, As, Ba, Pb, Cr, Hg, U, as well as

Martius Yellow, paraphenylene diamine, methyl alcohol, tetra- and other halogenated hydrocarbons.

Appendix xi

Spanish Legislation

In the "Decreto 2464/1963" (dated August 10, 1963) pharmaceutical legislation has been noted in which "Capitulo VIII" is concerned with the cosmetic field. As yet, it does not cover any technical details of the formulations.

Appendix xii

Swedish Legislation

There is as yet no specific legislation on toilet preparations in general, but such products are affected by the regulations for medicine and poison.

Medicine Regulations

Medicines are products which are intended to prevent, indicate, mitigate, or cure diseases or symptoms of diseases in people or animals. Whether a product shall be considered a medicine depends on the purpose of the product, not on properties. Medicine must be sold only in a chemist's shop.

A cosmetic product must thus not be advertised to have any curing or disease-preventing effect whatsoever. Certain toilet preparations may, however, be considered as "free medicines," which means that they can be sold in the open market and that certain limited statements can be made about curative effect, i.e., for a shampoo it is allowed to claim that it mitigates formation of natural dandruff. To get such advertising approved, the claimed effect has to be proved. It is proposed to have complete declarations on packages for the so-called "free medicines." Bactericidal toilet soap tablets are also included in this group.

Poison Regulations

The main concern of the poison regulations is "products dangerous to the health," which are divided into poisons and dangerous ingredients.

The following substances are classified as poisons:

1. Any substance which is used exclusively or mainly when making a

medicine and which is claimed to be considered as a poison by the Medical Board.

2. Any other substance dangerous to health, the handling of which involves considerable danger to health.

Preparations containing a poison or a dangerous substance, the danger of which exclusively or mainly is caused by such a substance, are also classified as substances dangerous to health. Whether or not a preparation is to be considered as a poison or a dangerous substance can be seen from the text in the legislation and in the papers from the preceding work which state that the primary judgment shall be valid if the preparation, on the whole, is to be considered a dangerous product. Preliminary lists of poisons and dangerous substances have recently been distributed by the Medical Board. The intention is that these lists shall be supplemented from time to time.

According to a proclamation from the Medical Board, valid as from January 1, 1964, certain substances used in cosmetic and hygienic preparations may no longer be used. The proclamation reads in translation:

> "Cosmetics or hygienic preparations may not contain poisonous material, hazardous dyes, methanol, paraphenylenediamine, para-aminodiphenylamine or paratoluylendiamine. Moreover, cosmetics may not contain substances intended for external use only obtainable against a doctor's prescription. Antiperspirants, deodorants and hair lotions may not contain formalin. Baby powder and baby ointments may not contain more than 10% boric acid."

Appendix XIII

Swiss Legislation

There is as yet no specific legislation on toilet preparations in general, but some are covered by regulations on consumer goods.

The "Verordnung uber den Verkehr mit Lebensmitteln und Gebräuchsgegenstanden" (26.5.36) mentions in XL Art. 467 (modified 19.04.40 and 27.01.56) "Kosmetische Mittel," which covers hair dyes (paraphenylene diamine is forbidden) and cold wave preparations (not more than 7% thioglycolic acid and pH $\leq$ 9.5), hair preparations (methanol) and cuticle removers.

There is a general prohibition of poisonous metals and nonmetals, and there is a positive list of dyestuffs for products in class "C" and "C-ext." Other colorants can be used by cantonal permission.

Products with curative properties are, in general, restricted to sale through pharmacies.

Appendix XIV

U.K. Legislation

The consumer is protected primarily by Common Law. Relevant legislation is also provided by the Pharmacy and Poisons Act of 1933 and the associated Poisons List and Poisons Rules, which are issued from time to time as laid down by the Act. The Pharmacy and Poisons Act contains the basic legislation for the administration of pharmaceutical operations and for the control of poisonous substances. The link between these two rests in the important position of the registered pharmacist as a controller of poisons. An important part of the Act is Section 18, which specifies who is entitled to sell products containing poisons and how they shall be labeled (Section 18, para. 1b and 1c); subsequent sections authorize the creation of the Poisons List and the Poisons Rules.

The Poisons List, which is continually under review, divides poisons into two main classes; Part I—Poisons which may be dispensed only by a pharmacist and with which cosmetic formulators are, generally speaking, not concerned, and Part II—Poisons which, with certain labeling and point of sale restrictions, are capable of being included in toilet preparations.

The Poisons Rules, which are also amended from time to time, treat Part II Poisons more specifically by applying particular regulations to them according to their properties and use. Of particular interest are the Third and Seventh Schedules; the former contains the exemptions, notable among which are:

Poisons	*Substance or Article in Which Exempted*
Chloroform	Substances containing less than 10% chloroform
Diamines, the following and their salts; phenylene diamines; tolylene diamines: other alkylated-benzene diamines	Substances other than preparations for the dyeing of hair
Formaldehyde	Substances containing less than 5% w/w of H CHO

Lead acetate	Substances containing less than 4% of lead acetate
Phenyl mercuric salts	Toilet, cosmetic and therapeutic preparations containing not more than 0.01% of phenyl mercuric salts as a preservative; antiseptic dressings and toothbrushes
Sodium fluoride	Substances containing less than 3% of sodium fluoride as a preservative

The Seventh Schedule contains in Para. 4 details of the labeling and words of warning required for hair dyes containing phenylene diamines and tolylene diamines.

The First Schedule (dealing with special restrictions) applies to acetarsol a limit of 0.5% in dentifrice and to cantharadin a limit of 0.01%; it restricts to pharmacy sale (*inter alia*) barium salts and thallium salts. The rulings on alkaloids are complex, but for certain alkaloids sale other than through a pharmacy is permitted at very low concentrations.

The only other statutory regulations with which cosmetic chemists may possibly be concerned are:

1. The Dangerous Drugs Act and its rules, which control the use of morphine and other habit-forming drugs.
2. The various regulations covering foodstuffs and in particular those regarding coloring matter (The Colouring Matter in Food Regulations, 1957). It should be appreciated, however, that in the United Kingdom dental preparations are not foods and although food colors may be used, where convenient and practical, there is no legal obligation to do so.
3. The Pharmacy and Medicines Act which defines (Section 17) a medicine in such terms (intended for the prevention or treatment of any ailment, infirmity or injury affecting the human body) as to include all toilet preparations of a therapeutic nature, (e.g., anti-dandruff shampoos, fluoride toothpastes, etc.) and demands (Section 11) labeling in such cases indicating nature and quantity of active ingredients.

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Replacement of Bromo Acids in Lipsticks by Water-Soluble FDC and DC Colors

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Presented before the Third Congress of the I.F.S.C.C., June 21-26, 1964, New York City

Synopsis—Water-soluble FDC and DC colors have found almost no application in lipsticks because of their insolubility in the usual lipstick bases and because they have no tendency to stain lips. It has now been found that the free sulfonic acids prepared from the FDC and DC colors have satisfactory solubility in fatty bases and produce adequate stain on the lips. It is shown that these dyes can be readily incorporated into a conventional lipstick base and that it is possible to create a fairly wide range of shades through exclusive use of FDC and DC azocolor acids.

Background

The color effect in lipsticks is obtained by using staining dyes to give some degree of indelibility, and pigments to give opacity and a full range of shades. Whereas no problems exist with the pigments, the more important staining dyes are suspected of causing certain difficulties. Staining dyes generally are halogenated fluoresceins, e.g., 2,4,5,7-tetrabromo-fluorescein, and are therefore referred to as "bromo acids."

The physiological properties of the bromo acids are strongly influenced by their impurities, which are more toxic than the pure dyestuffs, and many attempts have been made to produce bromo acids of higher purity. A British Patent (1) describes a method for producing purified bromo acids by a process in which the bromo acids are first

* Chemieberatung Dr. H. Wilmsmann, Laboratories, Heidenreichstr. 4, Darmstadt/W. Germany.

esterified with anhydrides, then extracted and finally hydrolized. The Toilet Goods Association (2) has published new specifications for D & C Orange #5 and #10 and D & C Reds #21 and #27, all of these colors being very important bromo acids. Bromo acids meeting these specifications represent the highest commercially available purity and are used in the pharmacological color testing program of The Toilet Goods Association.

In addition to the uncertainty of the outcome of the testing program, the bromo acids have the disadvantage of not fulfilling all expectations with regard to achievable range of shades. The shades obtained by the bromo acids are orange-red or pink and bluish-red, but pure red shades are missing.

For these reasons it would be highly desirable to have other dyestuffs available which might replace the bromo acids in lipsticks. Any attempts to develop such dyestuffs, however, must be planned very carefully. Even if new dyestuffs could be found which meet the requirements of solubility in lipstick bases and substantivity to lips, nobody can predict the result of the necessary physiological tests. Since these tests are very expensive and lengthy, one can understand that there is not too much enthusiasm for the research and development of new lipstick dyestuffs, especially if one considers the limited lipstick market.

Use of FDC and DC Colors

Attempts have been made to use those FDC and DC colors which do not belong to the fluorescein class and for which complete safety has already been established. These colors are of the azo and triphenylmethane series and possess almost no value for lipsticks because they are neither sufficiently soluble in lipstick bases nor do they exhibit substantivity to the lips, or both.

It was, therefore, surprising that a method for lipstick use of safe FDC and DC colors could be found. It has been shown that the FDC and DC colors of the azo type are very useful as staining dyes for lipsticks in the form of free sulfonic acids. All of the water-soluble FDC and DC colors are known, sold and used in the form of their salts, mainly as sodium, ammonium, potassium or calcium salts. In their salt forms they have no place in lipsticks because they are not soluble in lipstick bases and do not stain the lips. The free acids, however, have good solubility in lipstick bases and produce strong staining on the lips.

It should be expected that the extensive physiological testing program need not be applied to the free acids of the FDC and DC colors. These differ from the previously tested color salts only by replacement of

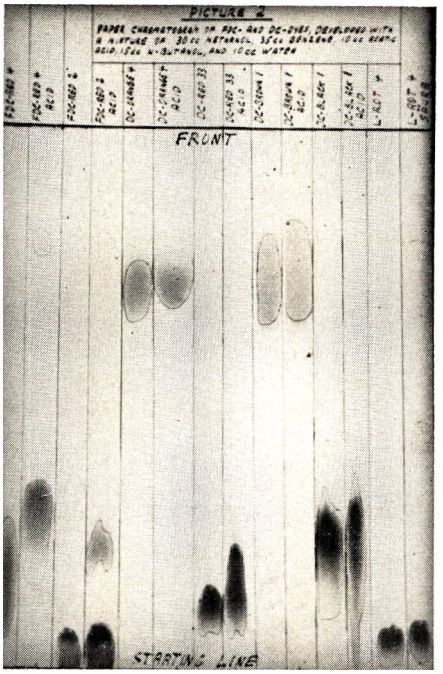

Figure 1. Paper chromatograms of FD & C and D & C dyes and corresponding free acids (cf. text for solvent system)

ammonium, sodium, potassium or calcium ions with hydrogen, and the pharmacological behavior of the dyestuffs depends only on the anion which remains the same. It is assumed, therefore, that there will be no severe difficulty in obtaining certification of the FDC and DC color acids of the azo class.

The chemical constitution of some azo color acids and the classification of the corresponding salts are given in Table I.

The production of the color acids is very simple and may be achieved by acidifying concentrated solutions of the corresponding color salts in water with strong acids. The free acids are much less soluble in water than the color salts and precipitate. After filtration and washing with dilute solutions of a strong acid in water (preferably hydrochloride acid), the color acids may be dried at about 120°C.

The analysis of the color acids produced by this method shows excellent purity. The content of inorganic salts as well as inorganic cations of the dye salts is almost zero, as determined by ashing.

The paper chromatogram (Fig. 1) demonstrates that the R_f-value of the acids is a little higher than that of the salts in a mixture of 30 cc.

TABLE 1

Chemical Constitution of Azo Color Acid	Color Index No.	Salts of Acid: Permitted as	Salts of Acid: Permitted in
1. 3-Carboxy-5-hydroxy-1-p-sulfophenyl-4-p-sulfophenyl-azo-pyrazole	19 140	FD&C Yellow No. 5	USA
2. 1-p-Sulfophenylazo-2-naphthol-6-sulfonic acid	15 985	FD&C Yellow No. 6 L-Orange 2	USA Germany
3. Mixture of 1-Alcylphenylazo-2-naphthol-3,6-disulfonic acids	16 155	Ext. D&C Red No. 15 C-Rot 18	USA Germany
4. 1-(4-Sulfo-1-naphthylazo)-2-naphthol-3,6-disulfonic acid	16 185	FD&C Red No. 2 L-Rot 3	USA Germany
5. 2-(5-Sulfo-2,4-xylylazo)-1-naphthol-4-sulfonic acid	14 700	FD&C Red No. 4 C-Rot 5	USA Germany
6. 1-Xylylazo-2-naphthol-3,6-disulfonic acid	16 150	D&C Red No. 5 C-ext. Rot 35	USA Germany
7. 4-(o-Sulfo-p-tolylazo)-3-hydroxy-2-naphthoic acid	15 850	D&C Red No. 6 C-Rot 12	USA Germany
8. 1-(4-Chloro-o-sulfo-5-tolylazo)-2-naphthol	15 585	D&C Red No. 8 C-ext. Rot 17	USA Germany
9. 2-(2-Hydroxy-1-naphthylazo)-1-naphthalene sulfonic acid	15 630	D&C Red No. 10 C-ext. Rot 33	USA Germany
10. 8-Amino-2-phenylazo-1-naphthol-3,6-disulfonic acid	17 200	D&C Red No. 33 C-WR Rot 2	USA Germany
11. 4-(1-Sulfo-2-naphthylazo)-3-hydroxy-2-naphthoic acid	15 880	D&C Red No. 34 C-Rot 14	USA Germany
12. 4-p-Sulfophenylazo-2-(2,4-xylylazo)-1,3-resorcinol	20 170	D&C Brown No. 1 C-Braun 2	USA Germany
13. 8-Amino-7-p-nitrophenylazo-2-phenyl-azo-1-naphthol-3,6-disulfonic acid	20 470	D&C Black No. 1 C-WR Schwarz 1	USA Germany
14. 1-(4-Sulfo-1-phenylazo)-4-aminobenzene-5-sulfonic acid	13 015	L-Gelb 1	Germany
15. 4-(4′-Sulfo-1′-phenylazo)-1-(4′-sulfo-phenyl)-5-hydroxypyrazolone-3-carboxylic acid	19 140	L-Gelb 2	Germany
16. 2,4-Dihydroxyazobenzene-4′-sulfonic acid	14 270	L-Gelb 4	Germany
17. 1-Phenylazo-2-naphthol-6,8-disulfonic acid	16 230	C-Orange 5	Germany
18. 1-p-Sulfophenylazo-2-naphthol	15 510	D&C Orange No. 4 C-Orange 2	USA Germany
19. 1-(3′-Sulfo-1′-phenylazo)-2-naphthol-6-sulfonic acid	15 980	L-Orange 1 Ext. D&C Orange No. 3	Germany USA
20. 1-(4′-Sulfo-1′-naphthylazo)-2-naphthol-6,8-disulfonic acid	16 255	L-Rot 4	Germany
21. 1-(4′-Sulfo-1′-naphthylazo)-2-naphthol-3,6,8-trisulfonic acid	16 290	L-Rot 5	Germany
22. 2-(6′-Sulfo-1′-m-xylylazo)-1-naphthol-5-sulfonic acid	14 815	L-Rot 6	Germany
23. ((4′-(4″-Sulfo-1″-phenylazo)-7′-sulfo-1′-naphthylazo))-1-hydroxy-8-acetylamino-naphthalene-3,5-disulfonic acid	28 440	L-Schwarz 1	Germany

TABLE I—*continued*

Chemical Constitution of Azo Color Acid	Salts of Acid		
	Color Index No.	Permitted as	Permitted in
24. ((4′-(4″-Sulfo-1″-phenylazo)-7′-sulfo-1′-naphthylazo))-1-hydroxy-7-amino-naphthalene-3,6-disulfonic acid	—	L-Schwarz 2	Germany
25. 1-(3′-Sulfo-1′-phenylazo)-2-amino-naphthalene-3,6-disulfonic acid	13 445	LB-Gelb 1	Germany
26. 4-(o-Sulfophenylazo)-1-(o′-sulfophenyl)-5-pyrazolone-3-carboxylic acid	19 120	C-Gelb 1	Germany
27. 1-(p-Sulfo-o-tolylazo)-2-naphthol	15 575	C-Orange 3	Germany
28. 1-Phenylazo-2-hydroxynaphthalene-6-sulfonic acid	15 970	C-Orange 4	Germany
29. 2-(Dehydrothio-4-toluidinesulfo-azo)-4-sulfo-1-naphthol	14 780	C-Rot 6	Germany
30. 2-Naphthylazo-5-sulfo-1-naphthol	14 830	C-Rot 7	Germany
31. 1-(3-Carboxy-4-chloro-6-sulfo)phenyl-azo)-2-naphthol	15 525	C-Rot 8	Germany
32. 1-(4-Sulfo-3-methylphenylazo)-2-naphthol	15 580	C-Rot 9	Germany
33. 1-(3-Sulfo-4-chlorophenylazo)-2-hydroxy-3-naphthoic acid	15 825	C-Rot 11	Germany
34. 1-(2-Sulfo-4-methyl-5-chloro-phenylazo)-2-hydroxy-3-naphthoic acid	15 865	C-Rot 13	Germany
35. 1-Naphthylazo-2-hydroxynaphthalene-6,8-disulfonic acid	16 250	C-Rot 19	Germany
36. 2-(3-Methylphenylazo)-1-hydroxy-8-benzoylaminonaphthalene-3,5-disulfonic acid	18 000	C-Rot 21	Germany
37. 2-(3-Chlorophenylazo)-1-hydroxy-8-(2′,4′-dichlorobenzoylamino)-naphthalene-3,5-disulfonic acid	18 020	C-Rot 22	Germany
38. 2-(2-Methoxyphenylazo)-1-hydroxy-8-(2′,4′-dichlorobenzoylamino)-naphthalene-3,5-disulfonic acid	18 025	C-Rot 23	Germany
39. 4-(3-Sulfo-1,7-dihydroxynaphthyl-2-azo)-4′-(3-sulfo-1-hydroxy-7-phenylsulfonyloxy-naphthyl-2-azo)-1,1′-diphenylcyclohexane	24 790	C-Rot 24	Germany
40. 2-(4-Aminophenylazo)-1,8-dihydroxy-naphthalene-3,6-disulfonic acid	16 580	C-Violett 1	Germany
41. 1-(2-Sulfo-4,6-dimethylphenylazo)-4-(1-hydroxy-3-sulfo-6-phenylaminonaphthyl-2-azo)-2-methyl-5-methoxy-benzene	27 905	C-Violett 2	Germany
42. 1-(2-Hydroxynaphthylazo)-2-hydroxy-4-sulfo-6-p-tolylsulfonamido-naphthalene	15 715	C-Schwarz 1	Germany
43. 1-(4-Phenylamino-5-sulfonaphthylazo)-4-(5-sulfonaphthylazo)-naphthalene	26 370	C-Schwarz 2	Germany
44. 1-(3,6-Disulfo-2-hydroxynaphthylazo)-4-(6,8-disulfo-naphthyl-2-azo)-naphthalene	27 260	C-Schwarz 3	Germany

methanol, 35 cc. benzene, 10 cc. glacial acetic acid, 15 cc. *n*-butanol and 10 cc. water as the mobile phase. The spots of the free acids, however, are less distinct and more diffuse than those of the color salts, due to their more versatile solubility in water and in organic solvents.

The FDC and DC color acids are easily soluble in organic solvents such as 1,2-propylene glycol, isopropyl myristate, castor oil and waxes, whereas the corresponding color salts are much less soluble or insoluble in these solvents. The relative solubilities in water are different, i.e., the color acids are less soluble than the color salts. The water-soluble azo color salts would normally be expected to show "feathering" on the lips. Because of the markedly reduced water-solubility of the acid form this does not occur. Thus when a solution of the color acids in castor oil is shaken with water, almost no color enters the water phase.

The FDC and DC azo color acids make possible the creation of a full range of shades. FDC Red #4 acid and L-Rot 4 acid produce pure red shades, which are not obtainable with the bromo acids. The acid forms of FDC Red #2 and of DC Red #33 may be of practical value as the sole staining dyestuffs and for toning.

The incorporation of the FDC and DC azo color acids into lipsticks is much the same as that of the bromo acids. In most cases, the lipstick bases may be used unchanged or only slightly modified. A typical formula follows:

Lipstick base:

51.6 g.	Isopropyl myristate
34.5 g.	Oleyl alcohol
24.2 g.	Lauric acid monoethanolamide
55.2 g.	Ozokerite
34.5 g.	Castor oil
200.0 g.	

Color solution:

20.0 g.	FDC or DC azo color acid
180.0 g.	1,2-Propyleneglycol
200.0 g.	

Preparation:

The hot color solution is mixed with the molten lipstick base and further processed according to known lipstick manufacturing procedures.

Lipsticks made in accordance with this procedure are stable on storage, do not bloom and impart the desired color to the lips, which lasts for 1–2 days, depending on the applied color intensity.

The properties and manufacture of the FDC and DC azo color acids are now being investigated by dyestuff manufacturers in the United States and Europe and may soon be commercially available. Patents are pending.

Summary

It has been found that the FDC and DC azo colors in the form of their free sulfonic acids are easily soluble in most conventional lipstick bases and are strongly substantive to the skin. They can, therefore, replace the bromo acids which are now in use in lipsticks. It appears that the FDC and DC azo color acids have versatility which enables creation of a full range of shades from yellow and pure red to violet shades.

(Received June 24, 1964)

References

(1) *Brit. Pat.* 852,057, Oct. 19, 1960.
(2) Bulletin No. 3602, The Toilet Goods Assoc., Inc., March 12, 1960.

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Book Reviews

MECHANISMS OF HARD TISSUE DESTRUCTION, edited by Reidar F. Sognnaes, American Association for the Advancement of Science, Washington, D. C. 1963. XIV + 764 pages, illustrated and indexed. Price $13.

This book is based on a symposium cosponsored by the American Association for the Advancement of Science Sections on Dentistry, Medicine and Zoology and by the International Association for Dental Research, American College of Dentists and American Dental Association. It contains twenty-six chapters by forty-eight authors and coauthors. The primary purpose of the symposium, hence, the book, was to examine the conditions under which mineralized structures are subject to destruction by various marine and subterranean organisms, as well as by the action of the giant cells typical of lacunar resorption and the oral bacteria responsible for tooth decay.

Chapters one, two and three consider rock-boring organisms, boring sponges and boring gastropods, respectively. Chapter four, ably written by the editor, and chapter five are concerned with destruction of dental hard tissue by attrition, abrasion and erosion. Chapters six to eleven are concerned with dental caries. Microstructural changes, chemical effects and factors influencing the initiation, transmission and inhibition of caries are presented. Chapters eleven to twenty-four consider bone, in the main, with particular emphasis on resorption. Chapter twenty-five discusses the possible role of chelation in biological systems, and chapter twenty-six concludes with a presentation on collagen metabolism. Summaries and useful references are presented at the conclusion of each chapter. The volume includes an author (including reference authors) and a comprehensive subject index.

Each of the chapters is written by one or more authors, expert in their respective fields. As expected with such a presentation, considerable variation in style and coverage is evident, with essentially all chapters limited to the specific subject of interest to the authors. The preface by the Editor recognizes this and includes an excellent summary and correlation of the various phenomena discussed.

The printing and photographs are

of excellent quality. Errors are infrequent. Those interested in the mechanisms associated with the dissolution of mineralized structures—rocks, corals, shells, antlers, bone, ivory, cementum, dentine and enamel—will be exposed to a rewarding presentation of the subject.—S. D. GERSHON—Lever Brothers Company.

THE EVALUATION OF THERAPEUTIC AGENTS AND COSMETICS, edited by T. H. Sternberg and V. D. Newcomber. McGraw-Hill Book Co., New York, N. Y. 1964. 293 pages, illustrated and indexed. Price $17.50.

This book is based on a postgraduate symposium held at the University of California School of Medicine several years ago. The volume contains 26 chapters contributed by more than 20 authors. From the impressive list of contributors the reader should expect some worthwhile and significant information; nevertheless, this book is a disappointment. Most of the material in the book is either of a review nature or has already appeared in slightly altered form in scientific periodicals. Admittedly, some of the chapters are interesting; on the other hand large portions of this book have no lasting scientific merit and should not have been printed. The editing could have been more careful; e.g., there exists no selenium disulfate (*sic*) shampoo (p. 178). To permit the statement, "The human eye was used to assess erythema . . . " (page 25) is inexcusable and is in sharp contrast with the sound recommendation that "Simplicity and directness . . . are preferable . . . "(page 70).

This volume is typical of the veritable flood of "monographs" which are, in fact, collections of short scientific articles usually delivered at conferences or meetings. This reviewer must agree with Eugene Garfield that such monographic books are of very dubious merit. Some of his objections and the reviewer's observations follow: Most of the information generally has appeared in a regular scientific journal before book publication; retrieval from books is much more difficult than from journals; publication is delayed; worthwhile material is diluted with trivia; high cost of books.

In conclusion then, it would appear wiser to publish the worthwhile papers of this (or any other) conference in recognized scientific journals, while the papers are still new contributions, and to relegate the clap trap to the circular file. Unfortunately, a large portion of this book belongs in the latter category. —M. M. RIEGER—Warner-Lambert Research Institute.

ENCYCLOPEDIA OF SURFACE ACTIVE AGENTS by J. P. Sisley and P. J. Wood. Volume II. Chemical Publishing Company, New York. 1964. 501 pages. $16.50.

This book, sold as Volume II, is in reality an expanded version of the

original book of the same name by the same authors and published in 1952. The book is divided into two parts. Part I touches only briefly on the development and properties of surface active agents but covers the classification system developed by the authors in detail. Part II is an alphabetical listing of commercial brands of surface active agents and is essentially the "encyclopedia" portion of the book. Each surfactant is followed by the name of the manufacturer, the composition, the author's classification, the solubility properties and a few broad applications.

Sisley's introduction was written in 1953, and it is a mystery to this reviewer why the book was not published before 1964. Unfortunately, due to this 11 year lapse, the book is already outdated. For example, there is nothing on the timely topic of biodegradability. All literature references antedate 1953, and many of the listings are obsolete.

A few of the chapters in Part I are so general as to be worthless. Chapter IV of Part I dealing with "Applications of Sulphonated Oils and Modified Detergents" consists of one page of text and might just as well have been deleted. Chapter V of Part I on "The Properties of Surface Active Agents" is a brief subjective comparison of the pros and cons for the selection of soap and/or synthetic detergents in laundry and other cleansing products. No conclusive data are presented.

On the other hand, Chapter VI, concerned with "Detergent Builders and Synergists," probably the best chapter in the text, adequately covers the role of various inorganic and organic chemicals used in laundry products to improve detergency, to build suds and to prevent soil redeposition. Chapter VII comprises the major portion of Part I and explains the author's classification of surface active agents. These are classified into 18 anionic categories, five cationic categories, four nonionic categories and numerous mixtures of these. Following each classification is a list of the corresponding commercially available products. The major manufacturing processes are described briefly, followed by an extensive bibliography.

The idea of such a classification and listing is excellent; however, as mentioned previously, it is unfortunate that many of the products listed are obsolete and that the listing is very incomplete. Approximately 70% of the well-known surface-active agents manufactured by some of the largest surfactant manufacturers are not listed; and in one instance, 50% of the products shown for one supplier are obsolete and are no longer offered commercially.

It is inexcusable that a book purporting to be an up-to-date "encyclopedia" could have passed editorial review and been released for publication with such obsolete and incomplete data. This book is not recommended for anyone who wants timely information on surface-active agents. —CHARLES FOX—Warner-Lambert Research Institute.

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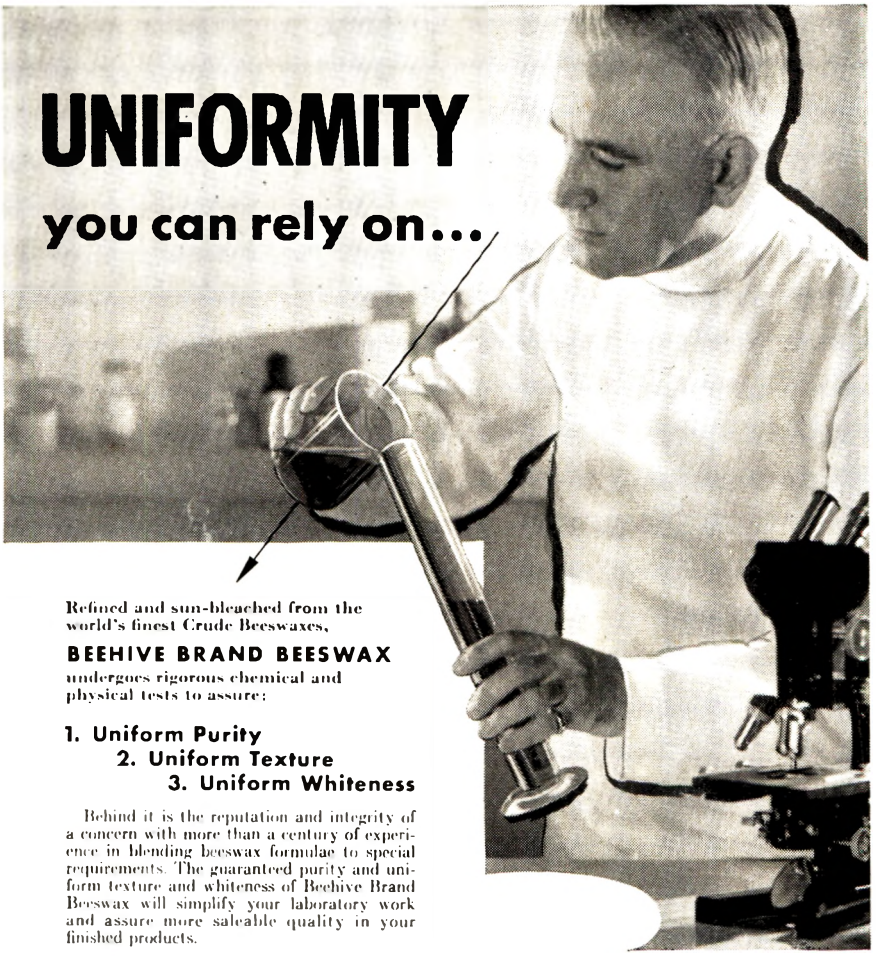

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