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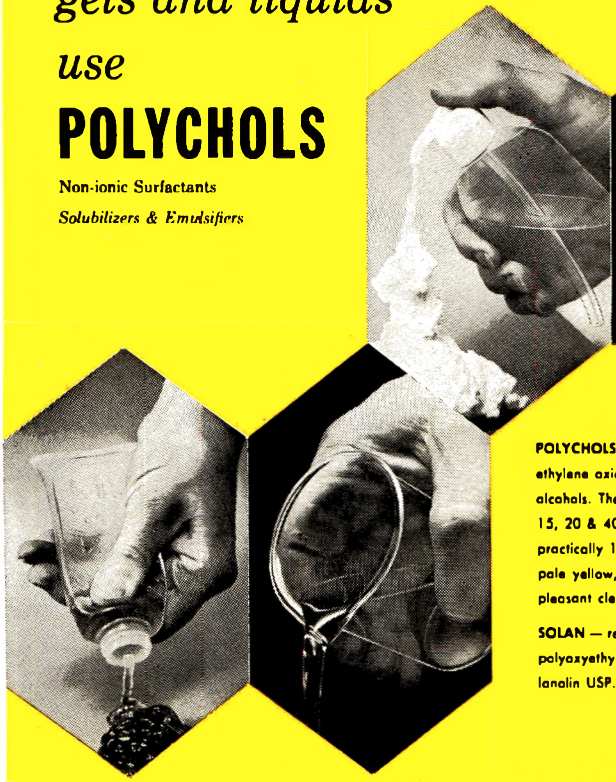
MARCH, 1963



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THE PHYSICAL BEHAVIOR OF WATER-SOLUBLE CELLULOSE POLYMERS

By J. B. Batdorf and P. S. Francis*

Presented December 4, 1962, New York City

Abstract

The commercially available ionic and nonionic water-soluble cellulose polymers are sodium carboxymethylcellulose, hydroxyethylcellulose and methylcellulose. These polymers impart varying degrees of non-Newtonian behavior to solutions. The physical properties of aqueous and mixed aqueous solutions of these cellulose ethers are governed by the chemical nature of their solubilizing substituents and are discussed with special emphasis on molecular structure.

From a modest start in the early 1920's, water-soluble cellulose ethers now make an important contribution to modern industry. Today, the commercial product line is formidable, and new products are constantly being added. The manufacturing process for each of these derivatives usually involves:

1. Formation of alkali cellulose
2. Reaction with suitable organic reagent
3. Neutralization
4. Purification
5. Drying

Typical reactions and products are shown in Fig. 1.

Small amounts of water-soluble cellulose ethers dispersed in water greatly modify its over-all properties. The most obvious immediate change is an increase in the viscosity of the water. An interesting aspect of this viscosity increase is the fact that a single solution will appear to have a wide range of viscosities when different conditions of physical force are imposed on the solution.

These conditions of physical force may be conveniently referred to as high, intermediate or low stress. For example, rolling or spreading a liquid as if it were an ointment or lotion would be high stress. On the other hand, after the liquid has been applied, gravity and surface tension control flow. These forces are conditions of low stress. Intermediate stress can be typified by pouring a liquid out of a bottle. Thus, if a solution of a water-

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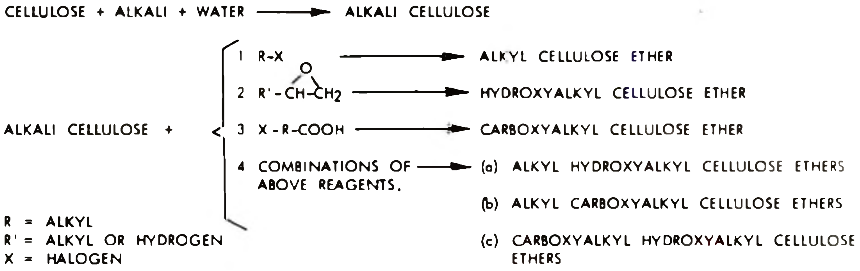


Figure 1.—Manufacture of cellulose ethers.

soluble cellulose ether appears to be a viscous syrup as it is poured from a bottle, it will behave as a runny liquid when applied as a lotion; yet, when high stress is removed it will instantly revert to a "molasses in January" consistency. These variations are pictured in Fig. 2. This type of flow behavior is referred to as pseudoplastic or non-Newtonian. There may also be a time-dependent consistency change usually called thixotropy. A different molecular weight or viscosity grade of polymer will behave in a similar fashion but to a different degree. The lower the molecular weight, the less change in viscosity will occur as stress conditions are varied. If viscosity does not change with stress, the solution is classified as Newtonian. Low molecular weight cellulose ether solutions are less pseudoplastic or non-

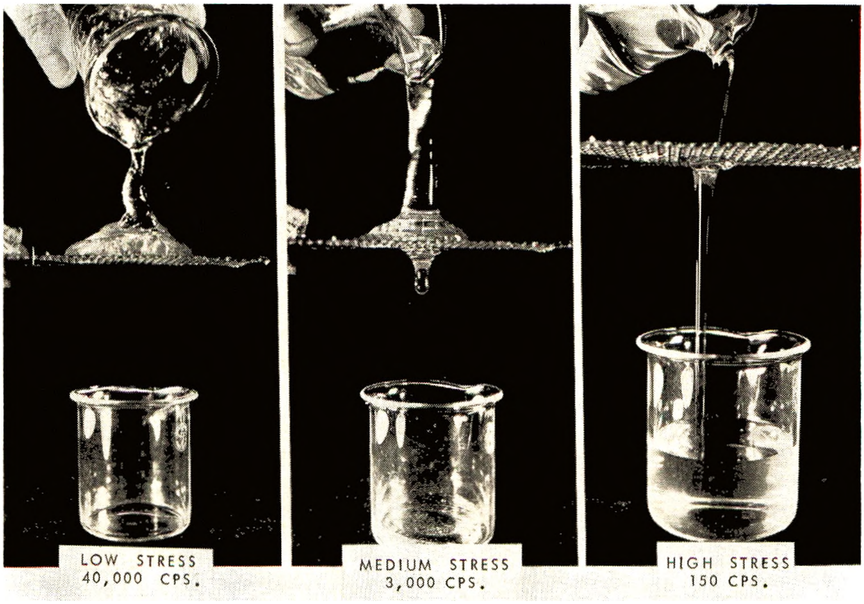


Figure 2.—A single pseudoplastic fluid acts differently under different conditions of stress.

Newtonian than the high molecular weight polymer solutions. These differences in viscosity-stress properties are shown in Fig. 3.

The foregoing discussion briefly shows how water-soluble cellulose polymers can impart divergent flow characteristics to water. Many of them also impart varied thickening properties to solvent systems other than plain water. Behavior of well-dispersed derivatives in these mixed solvent systems is similar to their behavior in water. However, the viscosity of the solvent must be taken into account. For example, if sucrose-water is the solvent and if this solvent is 50 times thicker than water, the resulting cellulose ether solution in the mixed solvent will be 50 times thicker than it will be in water. This behavior is predictable for many solvent-water mixtures, and is shown in Fig. 4.

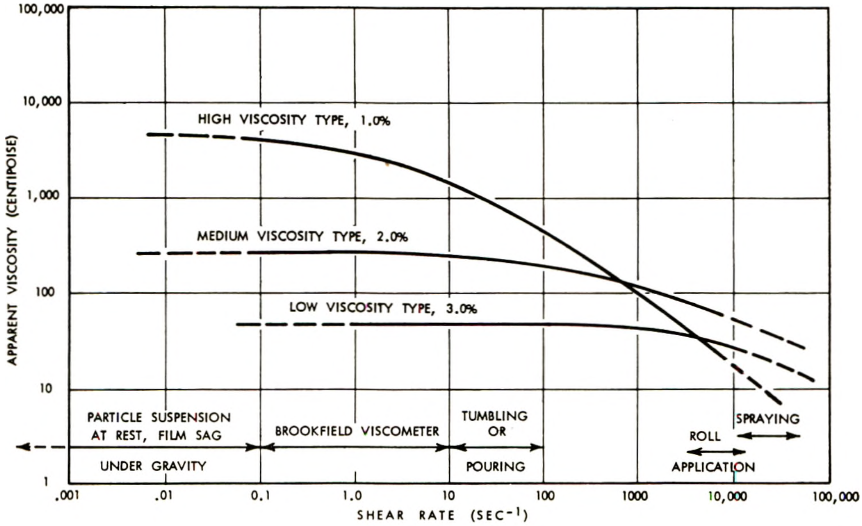


Figure 3.—Typical flow behavior of hydroxyethylcellulose.

In order to render cellulose soluble in solvent, chemical groups must be added. These substituents impart solvent attracting characteristics to the cellulose and act as wedges to force the cellulose molecule apart and break its inherent physical bonds. Some of the groups which make cellulose hydrophilic (water attracting) are shown in Fig. 5. Also shown are representations of how water is believed to interact with these groups. The ionic groups, which separate into positive and negative components, provide a strong dissolving force. The components with positive charges migrate away from the cellulose chain, leaving only negative charges. Since like charges repel, the cellulose chain expands and exposes hydrophilic sites to the solvent. The nonionic groups provide dissolving power

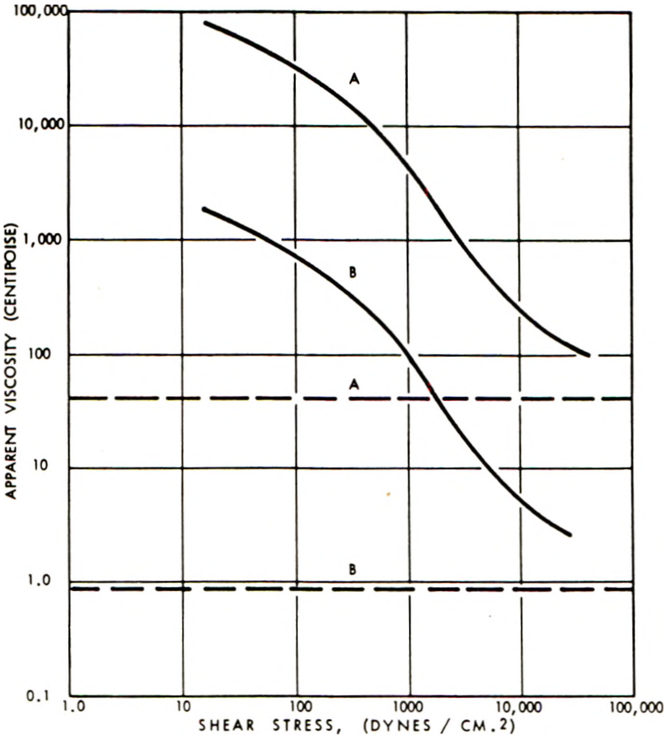
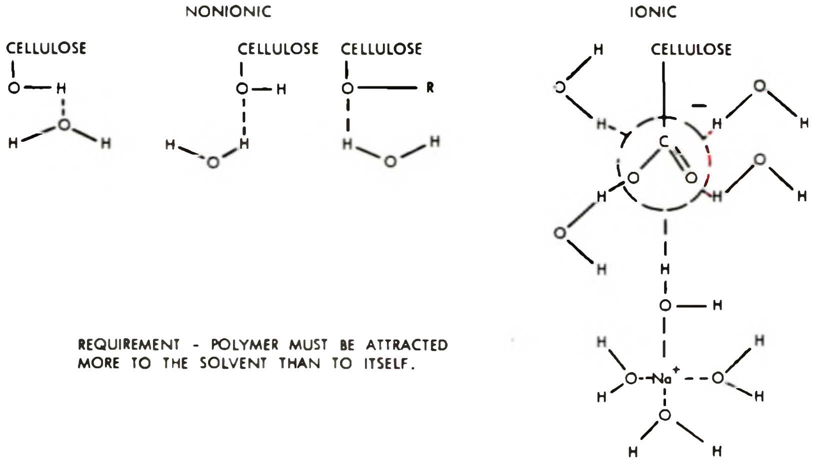


Figure 4.—Flow behavior of well-dispersed carboxyalkyl- and hydroxyalkylcellulose ethers in (A) sucrose-water and (B) water solid; curves are solutions; broken curves are solvents.

mainly by hydrogen bonding with the solvent. The oxygen and hydrogen of the solvent interact with like groups in the polymer. Figure 6 summarizes the hydrophobic (or water-repelling) and the hydrophilic groups of typical ionic and nonionic water-soluble polymers.

Many of the physical properties imparted to aqueous solutions by hydroxyalkylcellulose are governed by the chemical nature of its solubilizing substituent. When ethylene oxide is added to cellulose, no hydroxyl groups are lost. They are merely transferred to the end of the substituent. Such a derivative is more hydrophilic than alkyl cellulose derivatives, which have far fewer hydroxyl groups. This fact can be used to explain why alkyl celluloses precipitate at elevated temperature, whereas hydroxyethylcellulose does not. Figure 7 depicts the solvent water interacting with hydrophilic ether and hydroxyl groups. These hydrophilic groups are separated by hydrophobic ethylene groups (—CH_2-CH_2—). At normal room temperature, it is suggested that these chains are relatively motionless, as depicted by the uppermost structure in the figure. However, as the temperature increases, the hydrophobic group becomes excited and begins to vibrate between the ether linkages in some-



REQUIREMENT - POLYMER MUST BE ATTRACTED MORE TO THE SOLVENT THAN TO ITSELF.

Figure 5.—Forces for dissolving hydrocolloids in water.

what the same manner as a jumping rope. In essence, the hydrophobic volume increases, causing the hydrophilic ether linkages to become less accessible to the water solvent. A similar mechanism is shown at the bottom of Fig. 7 for an alkyl cellulose ether. Since the hydroxyethylcellulose has terminal hydroxyl groups which are not affected by this increased hydrophobic sphere, it remains soluble even at the boiling point of water. In the alkyl cellulose ether, insufficient terminal hydroxyls are available to keep the polymer soluble as the hydrophobic volume of the alkyl substituent increases. At some point (or temperature) the derivative precipitates from water. If the water is made a poorer solvent, for instance by adding salt to it, we can demonstrate the same phenomenon with hydroxyethylcellulose as is exhibited with alkyl cellulose in plain water.

Another interesting fact about the solubility of hydroxyethylcellulose is its relative solubility in solvents containing salts with multiple ionic charges. It has been found that hydroxyethylcellulose is less soluble in solutions containing multiple negative charges than in solutions containing

AQUEOUS SOLUBILITY FACTORS

DECREASING THERMAL STABILITY IN WATER

POLYMER	NO. OF HYDROPHOBIC GROUPS / UNIT	NO. OF ETHER GROUPS/UNIT	NO. OF -OH GROUPS/UNIT
CARB. ALKYL CELL.	NONE	1.0	2.0
HYD. ALKYL CELL.	1.5 $-CH_2-CH_2-$	1.5	3.0
HYD. ALKYL CELL.	2.5 $-CH_2-CH_2$	2.5	3.0
ALKYL CELLULOSE	~ 2 $-CH_3$	~ 2	~ 1

Figure 6.—Aqueous solubility factors.

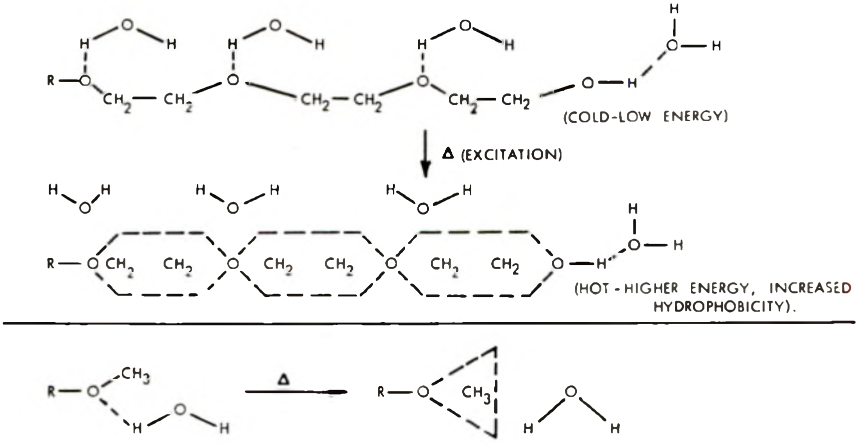


Figure 7.—Factor governing interaction of ether links with water.

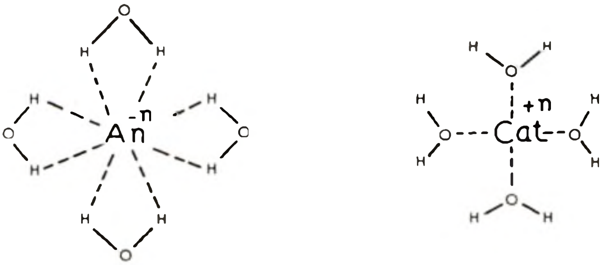


Figure 8.—Suggested action of polyvalent ions.

multiple positive charges. As shown in Fig. 8, it is proposed that the solvent molecules orient themselves so that fewer solvent hydrogens are available for associating with the cellulose molecules through its ether (C—O—C) linkages.

These examples only suggest the versatility and sophistication of the water-soluble cellulose ethers. They serve to suggest that, whereas a single sample may not perform as desired in an end use, many other variations of cellulose ethers exist which may turn the trick. The formulator is advised to seek information and assistance from the manufacturer of the cellulose ether in question before embarking on a program involving complex aqueous systems.

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FACTORS INFLUENCING THE SELECTION OF SUSPENDING AGENTS

By CLIFFORD W. CHONG*

Presented September 20, 1962, Seminar, New York City

WHEN DEVELOPING a suspension form of a drug, the formulator is faced with a number of problems. One of these is choosing the right suspension vehicle for his formula. In many cases, the choice of the vehicle is governed by what has been used in previous suspension products or by what has been described in the literature as having been tried and found useful, however usually in specific applications. This practice of following the dictates of convention does provide a starting point, but it has often led to the failure of many suspension systems. The reason for this is the complex nature of suspension systems. Higuchi (1), in his discussion of the physico-chemical aspects of suspension formulation, points out the difficulties one might expect when relating experimental data with suspension performance.

The formulator encounters a great number of variables when working with suspensions. There are, for instance, the physical properties of the particle, such as the size, shape and density, the density of the vehicle, the volume ratio of the two phases, the extent of particle flocculation, the flow characteristics of the suspension and, probably more important, the flow characteristics of the suspension vehicle. In addition, the variables which influence the chemical stability of the suspension must be considered. Because of these many variables, it seems unlikely that a vehicle used satisfactorily in one suspension formula could be equally as effective in another, unless the physical and chemical properties of both happened to be the same. For this reason, each suspension formula should be considered separately, depending upon the rheological and physico-chemical requirements of the formula.

This paper presents a method for evaluating suspension vehicles relevant to specific suspension formulas. The method is based on the rheological requirements of good suspension vehicles and the factors which influence the selection of the most effective vehicle. Also, a check-list is

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proposed for formulating suspensions with the minimum of phase separation.

RHEOLOGICAL REQUIREMENTS

From a practical viewpoint, a good suspension vehicle is one which is both "thick" enough to suspend particles and "thin" enough to shake and pour easily. The balancing of these two requirements is difficult and has long been one of the more perplexing problems in the formulation of suspensions. In order to gain a better understanding of the rheological requirements of a good suspension vehicle, the conditions under which the vehicle should be thick and those under which it should be thin will be considered briefly.

When a suspension is at rest the particles tend to settle under the influence of gravity. The vehicle, then, should be thick so as to prevent or retard the movement of the particles. When the suspension is shaken and then poured, the vehicle should be thin to permit these operations to be done with ease. We are concerned, therefore, with two conditions involving the magnitudes of shearing stress to which the suspension is subjected after it is prepared (2, 3): namely (1) the low shearing stresses accompanying the settling of the particles, and (2) the higher shearing stresses caused by shaking and pouring the suspension.

The shearing stresses resulting from particle sedimentation are usually of a low order. For small, spherical particles whose density differs only slightly from that of the vehicle, these stresses can be calculated from basic principles. The total force (F_T) of a particle of radius r, volume V_s, and density ρ_s, suspended in a vehicle of density ρ_v, is related to the upward (F_u) and downward (F_d) forces acting upon the particle. Hence,

$$F_T = F_d - F_u = V_s\rho_s g - V_s\rho_v g \tag{1}$$

or

$$F_T = 4/3\ \pi rg\,(\rho_s - \rho_v) \tag{2}$$

where g is the gravitational constant. In terms of shearing stress (τ, the force per unit area), the equation becomes

$$\tau = {}^1/_3\, rg\,(\rho_s - \rho_v) \tag{3}$$

Plots of shearing stress against particle radius for various differences in densities between the particle and vehicle are shown in Fig. 1. It can be seen that for particles usually found in suspension the shearing stresses are small (< 20 dynes/cm.^{2}). Consequently, the rates of shear resulting from the movement of these particles through the vehicle are proportionately small, depending upon the viscosity of the suspension.

The higher shearing stresses induced by shaking and pouring the suspension may vary markedly. They depend upon the force applied, the size and shape of the container and the air space in the container. No precise measurements have been made of these shearing stresses but they are believed to be approximately 100 to 600 dynes/cm.^{2} and 25 to 150 dynes/cm.^{2} for shaking and pouring, respectively.

When the different conditions of shearing stress are understood, it becomes readily apparent why a good suspension vehicle should be both thick and thin. Also, it is obvious that in formulating suspensions with the minimum of phase separation the conditions of low rates of shear should be of prime concern. This is where measurements of the rheological behavior of suspension vehicles should be made. The higher rates of shear should also be considered, but the measurement of these conditions is unnecessary as long as the suspension can be shaken and poured with ease.

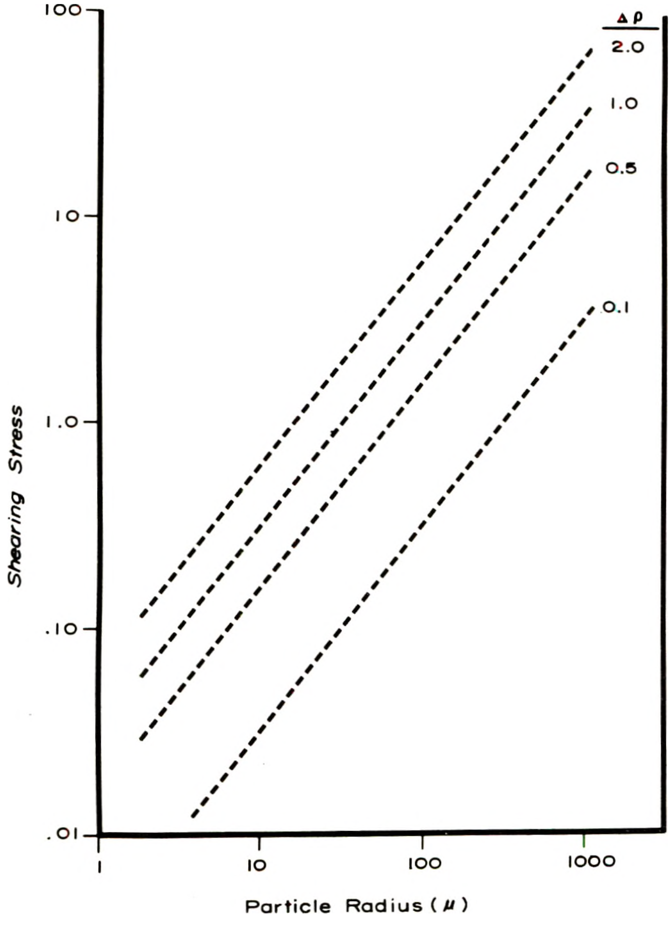

Figure 1.—Shearing stresses of particles (spheres) settling under the influence of gravity.

In summarizing the first portion of the discussion, we can say that the rheological requirement of a good suspension vehicle is (1) that it have infinitely high viscosity at low rates of shear or under the conditions when particle sedimentation would occur and (2) that it have low viscosity at the higher rates of shear or when the suspension is shaken and poured. With this in mind, it is possible to construct a hypothetical flow curve of shearing stress against rate of shear of a suspension vehicle having the desired rheological properties. In doing so, however, we find that such a curve would be similar to that of ideal plastic flow. This is shown in Fig. 2.

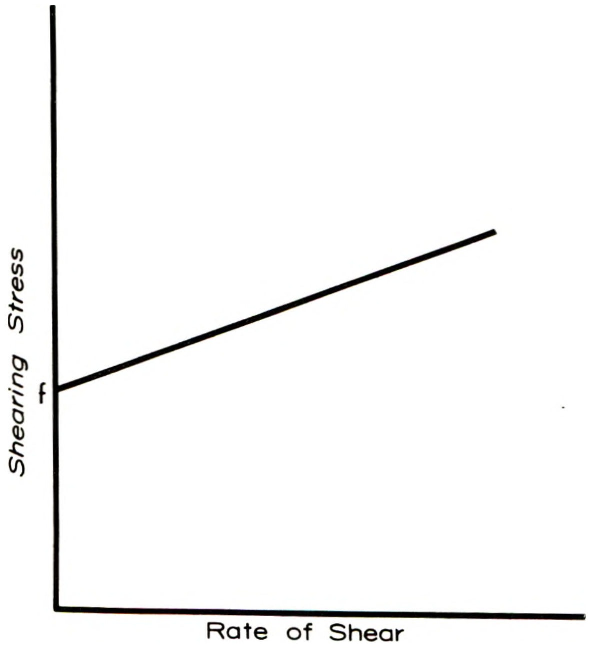

Figure 2.—Flow curve of ideal plastic flow.

An ideal plastic fluid is unique in that it will flow only after the applied shearing stress exceeds a minimum value. This minimum shearing stress is called the yield stress of the fluid and is indicated by the intercept *f* on the stress axis (Fig. 2). When referring to dispersed systems, yield stress may be defined as the resistive force of a fluid which prevents or retards the motion of particles in the fluid.

It is obvious that a suspension vehicle with ideal plastic behavior is most desirable. In addition to fulfilling the viscosity requirements, it possesses a yield stress which has been found to contribute to the suspension quality of the vehicle. The search for such a vehicle would be fruitless, however, since ideal plastic behavior is seldom, if ever, found among the suspension vehicles used in pharmacy and the cosmetic industry. Nevertheless, we can adopt the unique features of ideal plastic flow as criteria by which to evaluate suspension vehicles. Any approach to this type of flow behavior, therefore, could be considered a step toward attaining the ideal suspension vehicle.

In Fig. 3 are shown the flow curves of three suspension vehicles which differ in type of flow: (A) a pseudoplastic vehicle; (B) a thixotropic vehicle; and (C) a Bingham plastic vehicle. The curve for ideal plastic flow is included merely for comparison. It can be seen that the flow curve of vehicle C, the Bingham plastic, most closely approximates that of the ideal plastic. Thus, according to our criteria, the Bingham plastic vehicle C should be the best of the three. The thixotropic vehicle B should be rated second, and the pseudoplastic vehicle A last. There may be some question as to whether vehicle C or vehicle B should be placed first, because of the relative positions of the flow curves and the presence of a hysteresis loop (in vehicle B) which has been considered important for good suspension properties (4). The reason for this disagreement may be based on the interpretation of the thixotropic flow curve.

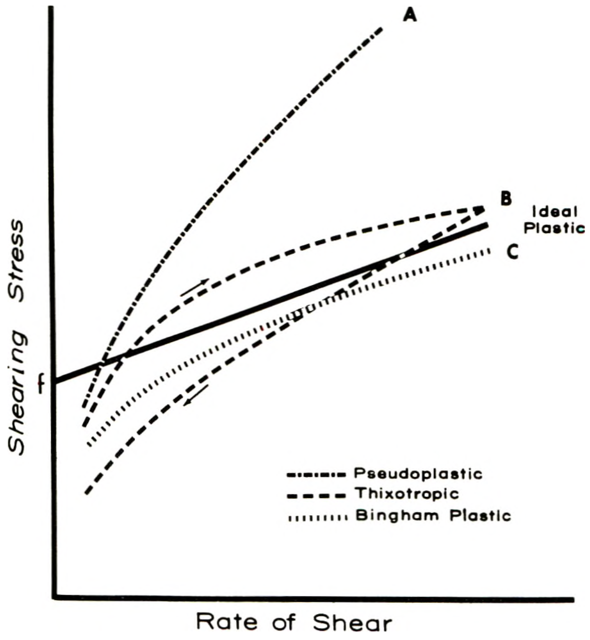

Figure 3.—Typical flow curves of non-Newtonian suspension vehicles.

Thixotropic flow is described by two flow curves, an upcurve and a downcurve. The two curves meet at a point of maximum shear. The upcurve describes the breakdown of internal structure as the vehicle is being sheared up to the maximum value. The downcurve, on the other hand, represents the flow characteristics of the vehicle after it has been subjected to maximum shear. In determining the suspension quality of the vehicle, we are concerned mainly with the conditions soon after the maximum shear has been applied, since this is when the particles begin to settle. If we assume, therefore, that the maximum shear described in the flow curves corresponds to the high shear of mixing during preparation of the suspension or to the shear induced by shaking and pouring the suspension during its use, it seems reasonable to consider only the downcurve for the measure of suspension quality.

The upcurve may also represent the gel state of the vehicle. For many thixotropic vehicles, this state may take hours or even days to reach. Therefore, if the upcurve is used to measure suspension quality, some of the measuring would be done long after the particles have begun to settle. By this time, and if the downcurve is such that it denotes poor suspension qualities, the particles may have settled markedly. The upcurve, then, could be used as a measure of suspension quality only if the thixotropic vehicle recovers its gel state within a very short time. The flow curve of such a vehicle, however, would appear similar to that of a Bingham plastic vehicle.

Before proceeding, I would like to clarify a point. It may seem that, from my foregoing discussion, thixotropic vehicles, in general, are inferior to Bingham plastic vehicles. This is not always true. I merely wish to point out that in the specific example shown, the Bingham plastic (Fig. 3, curve *C*) appears more desirable than the thixotrope (Fig. 3, curve *B*). Certainly, if a more concentrated thixotropic vehicle was used, such that its downcurve was positioned above the flow curve of the Bingham plastic, the thixotrope would be the vehicle of choice, provided, of course, that in its gel state it is not too thick to shake and pour.

Bingham plastic flow is distinguished by the need of a finite yield stress required to initiate flow. It differs from ideal plastic flow in that after the yield stress has been exceeded, the rate of shear is not a linear function of the shearing stress. Instead, the flow curve is concave to the rate of shear axis. This is similar to pseudoplastic flow except that at low rates of shear the curve appears to intersect the stress axis, indicating the presence of a yield stress, and at higher rates of shear the slope of the curve is usually small, indicating low viscosity. Unlike the ideal plastics, Bingham plastics do exist among the suspension vehicles which have potential use in pharmaceutical and cosmetic products. There may be some difficulty in finding them, however, because of the lack of reliable methods for detecting this type of flow behavior.

MEASUREMENT OF SUSPENSION QUALITY

In the process of screening potential vehicles for suspensions, we found that yield stress was largely responsible for the suspension qualities of a vehicle. Because of this, we found it necessary to develop methods which could provide reliable measures of yield stress. These methods will not be discussed at this time, but they will be presented in a forthcoming paper (5). Nevertheless, I would like to present to you the relationship which we found useful for determining the yield stress of non-Newtonian vehicles.

I. For pseudoplastic flow:

$$\tau = AD + Be^{-kD} \tag{4}$$

II. For Bingham plastic and thixotropic flow (downcurve):

$$\tau = (2UfD)^{1/2} + f \tag{5}$$

where τ is the shearing stress, D the rate of shear, U the plastic viscosity, f the yield stress, and A, B, and k are constants. By using these relationships, we obtained reliable measures of yield stress which showed good correlations with actual performance tests using glass and nylon beads of known sizes and densities.

PHYSICO-CHEMICAL FACTORS

Having dealt with the rheological aspects of suspension formulation, let us consider some factors which may influence the performance of suspension vehicles. These factors are:

1. Concentration
2. Ionic charge
3. pH
4. Temperature
5. Compatibility with substituents normally used in suspensions.

CONCENTRATION

Quite often the suspension properties of a vehicle can be enhanced significantly by slightly increasing the concentration of the suspending agent. This effect is shown in Fig. 4 for a typical Bingham plastic vehicle. It can be seen that as much as a twofold increase in yield stress can be achieved when only an additional 15 % of the suspending agent is used. This small increase in the suspending agent concentration may be the difference between a good and a poor suspension vehicle.

The data shown in Fig. 4 could facilitate the selection of suitable concentrations of the suspending agent, if the effective settling force of the particles is known. Also, since economics, to a large degree, governs the marketability of a suspension product, this information could aid in determining the minimum amount of the agent required for effective suspending action.

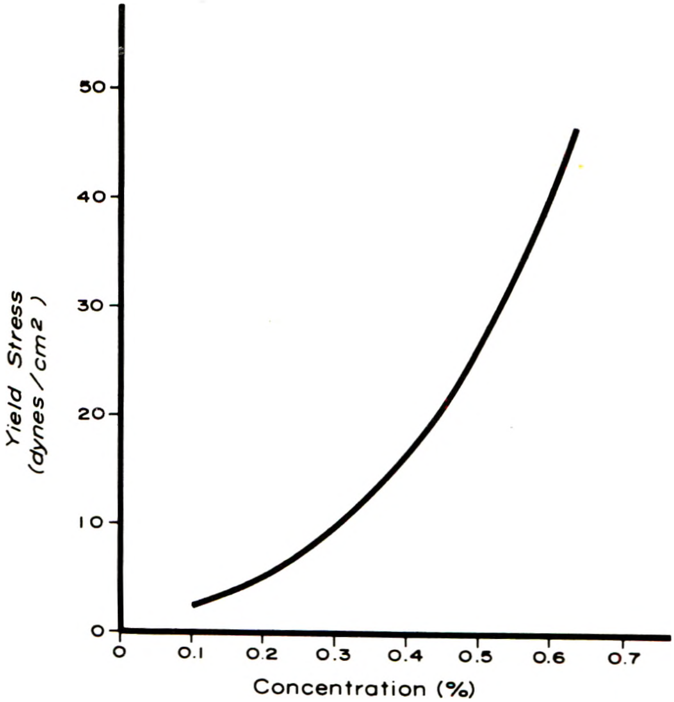

Figure 4.—Effect of concentration upon the yield stress of a Bingham plastic suspension vehicle.

Ionic Charge

It is important that the ionic charge of the suspending agent is known. Very often the use of a suspending agent and a drug of opposite charges results in unwanted effects. These effects are usually evidenced as a suspension which has settled rapidly, has decreased in drug potency or is altered in color, taste or over-all effectiveness. For this reason, the suspending agent should be one with the same charge as the drug or, preferably, one which is nonionic.

pH

In Fig. 5 is shown the effects of pH upon the yield stress of a suspension vehicle with Bingham plastic flow properties. It is evident that maximum suspension performance is achieved between pH 6 and 10. If it is necessary that the final pH of the suspension be less than 6 (or greater than 10) for reasons of drug stability, solubility or compatibility, then this vehicle should not be used. Instead, a vehicle which is not pH sensitive or one which is most effective at the desired pH should be selected.

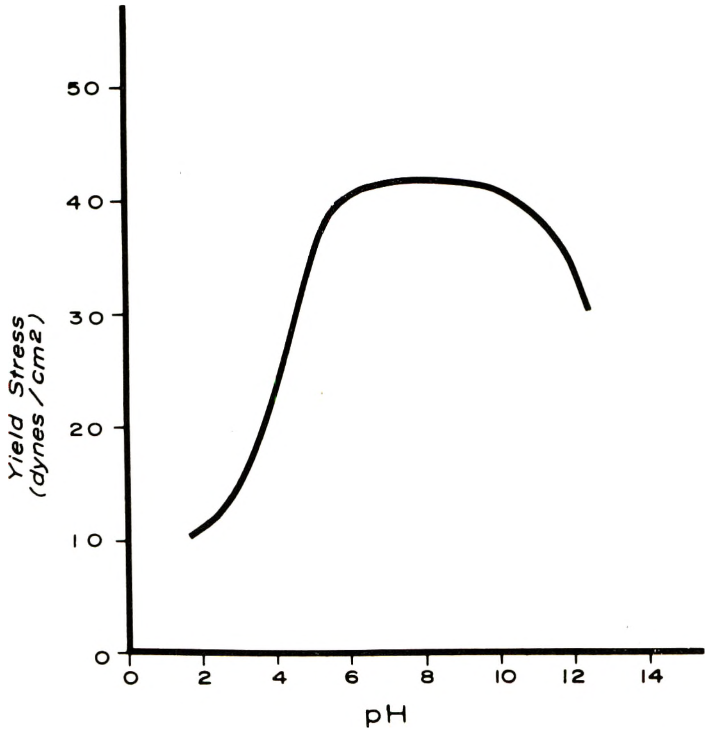

Figure 5.—Effect of pH upon the yield stress of a Bingham plastic suspension vehicle.

TEMPERATURE

A good suspension vehicle should not be affected by temperatures normally experienced by suspension products. At high temperatures, i.e., up to 60°C., the vehicle should not become so thin that it permits the particles to settle rapidly. Also, the vehicle should be able to recover its original consistency after being subjected to repeated freeze-thaw cycles.

COMPATIBILITY

The suspension vehicle should be compatible with every ingredient used in the suspension formula. That is, in addition to the drug(s), it should not be affected by the agents used to sweeten, color and flavor the product or by any other substance in the preparation.

CHECK-LIST FOR SUSPENSION FORMULATION

This check-list is presented to serve as a guide in the development of suspension products. The step-by-step procedures of the check-list could enable the formulator to exercise better judgment in selecting the most suitable suspending agent, and, also, the most effective concentration of the agent for his formula. In doing so, he can minimize the trial and error procedures of suspension formulation.

To make full use of the check-list the formulator should have prior knowledge of the physical and chemical properties of the drug he is to suspend. Also, he should be cognizant of the possible effects of the other ingredients in his formula, even though they may be present in small amounts. With this knowledge he will be forewarned of whatever effects each ingredient may have upon the rheological properties of the suspension vehicle. I would like to emphasize that this check-list is based on experiences gained with aqueous suspensions. There is reason to believe, however, that it might also apply to non-aqueous suspensions, provided that the same physico-chemical factors, either whole or in part, are inherent in these systems as well.

In light of the foregoing discussion the following procedure for formulating suspensions is suggested:

1. *Determine the ionic character of the drug (s).*

2. *Determine the ionic character of each of the other ingredients in the formula.* Whenever possible, use nonionic ingredients.

3. *Determine the density of the drug and the size of the largest particle to be suspended.*

On the basis of the information gained from steps 1 to 3, select the suspending agent(s) best suited to the formula. Since yield stress is an important and necessary factor in good suspending action, it is advisable, also, to choose the agent with this property.

4. *Determine the resulting density of the suspension medium*, after incorporating the suspending agent and the bulk ingredients, e.g., sucrose, sorbitol, etc. in the formula.

5. *Determine the sedimentation force of the particles.* From equation 3.

6. *Select the suspending agent and the concentration of the agent on the basis of the yield stress requirements of the formula.* In order to prepare a suspension with the minimum of phase separation the yield stress of the vehicle must be in excess of the sedimentation force of the particles. This excess should be sufficient to account for the unpredictable effects associated with concentrated suspension systems. It should also counteract the effects of vibration and temperature variation incurred during transit and storage of the suspension. There is no precise, calculable method by which these effects may be corrected for, but it is possible, quite satisfactorily, to offset them by using several times the required yield stress of the suspension system.

7. *After selecting the suspending agent and establishing the concentration of the agent to be used, formulate the suspension medium.* Check the rheological behavior of the medium before adding the powdered drug to

be sure that the desired properties are still present. If, for instance, upon the addition of sucrose to a suspension vehicle, there is a decrease in yield stress, more suspending agent should be added to make up for the loss. If, on the other hand, an increase in viscosity is shown when sucrose is added, the suspension may be formulated as such as long as the yield stress remains unaffected and the product is not too thick.

In general, the rheological behavior of the suspension should be checked at the various stages of formulation, particularly after the addition of each ingredient. If there is no significant change in rheological behavior, or if the rheological properties of the suspension can be restored to their original state without further change, this is an indication that the suspension may have good shelf-life stability.

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CLINICAL EVALUATION OF ANTIDANDRUFF FORMULATIONS

By Herbert J. Spoor, Ph.D., M.D.*

Presented September 19, 1962, Seminar, New York City

Dandruff is the common name given to the scalp conditions produced when the continuous but normally imperceptible sloughing of the outer epidermal layers of the skin becomes grossly visible. The scale consists of desquamated epidermal cells, accumulated secretions and acquired soil. When there is no obvious overactivity of the oil producing sebaceous glands, the condition is called Pityriasis capitis or Seborrhea sicca; with excess oil production it becomes Seborrhea oleosa and if it is accompanied by an erythematous or eczematized involvement of the outer skin itself it becomes seborrheic dermatitis. Figure 1 illustrates this sequence.

Antidandruff preparations are intended for treatment of Seborrhea sicca (a) and Seborrhea oleosa (b). However, if the condition has progressed either through local eczematization (c) or has spread to other body areas of predilection (d), more than topical therapy is often required to achieve control.

The mechanics of dandruff formation are best illustrated in a cross sectional view of the skin. Normally, the gradual sloughing of the dead and hardened outer epidermis exactly balances the constant production of new cells from the germinal layer below. Figure 2, which shows comparative photomicrographs of the skins of several animals and man, illustrates that this property of continuous growth is common to all animal skins, but it also shows human skin differs from that of the lower animals. In the human, there are more layers of viable and partially viable cells between the living, germinative basal layer of the epidermis and the tough, outer, fully keratinized layer, and therefore, any disturbance in the balance established between the constant production of new cells and the rate of sloughing of the old may produce visible masses of epidermal cellular debris that we call "dandruff." This is not identical to animal "dander" which consists primarily of keratin flakes. Most animal skins do not have the relatively thick, tough epithelium characteristic of man but depend for their strength upon a more fibrous, more heavily haired subepidermal

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* Cornell University, College of Medicine, Ithaca, N. Y.

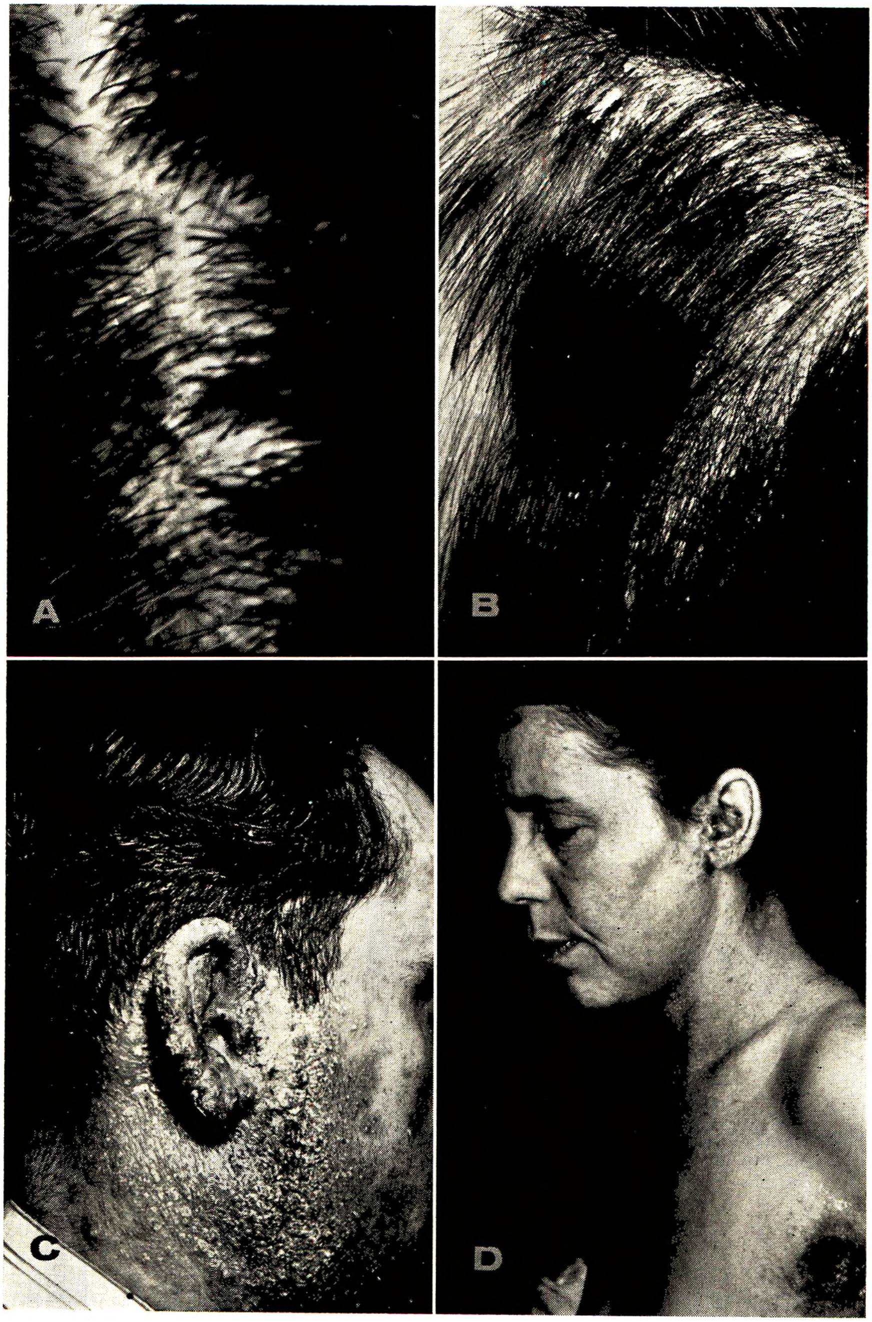

Figure 1.—Seborrheic diathesis. (A) Seborrhea sicca. (B) Seborrhea oleosa. (C) Seborrheic eczema—local. (D) Seborrheic eczema—other areas.

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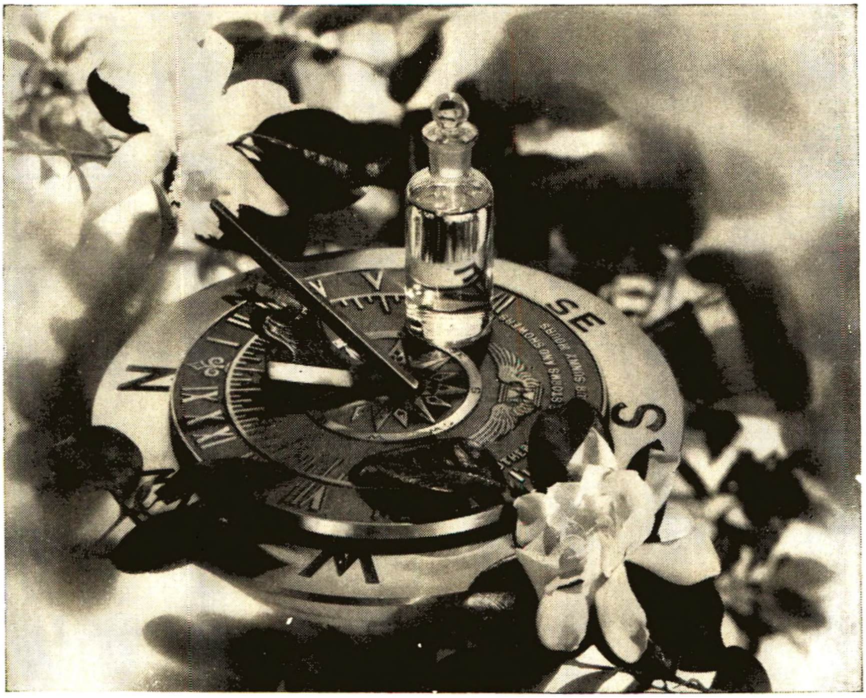

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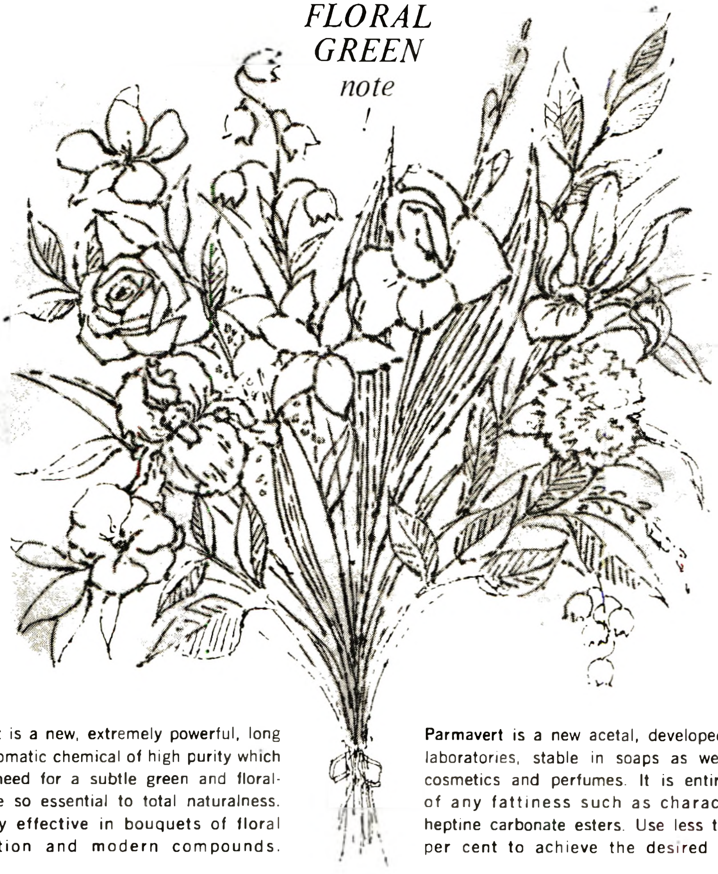


TYPICAL FORMULATIONS
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cutis. Another basic structural dissimilarity that may be responsible for a difference in epidermal desquamation is the relative lack of sweat glands in the animal skin, except in special areas. Animals like the cat and dog do not regulate their body temperature by evaporation of water from the entire body surface; hence there is no flow of water to wash continuously against and through the cellular structure, as is the case with the human epidermis. It is quite apparent from Fig. 2 that rabbit and guinea pig skins are very different from human skin. The epiderms are so thin that it takes an extremely competent technician to obtain an adequate section. Calf skin approaches human more closely, but the hair structure is quite different. Pig skin, in thickness of epidermis is quite comparable to human, but the bristle structure is totally foreign. Normal human skin has a reasonably consistent epidermal thickness varying from 0.06 to 0.09 mm. except on the palms and soles (1), and is structurally quite similar in the infant and adult except for acquired maturity of dermal fibers. However,

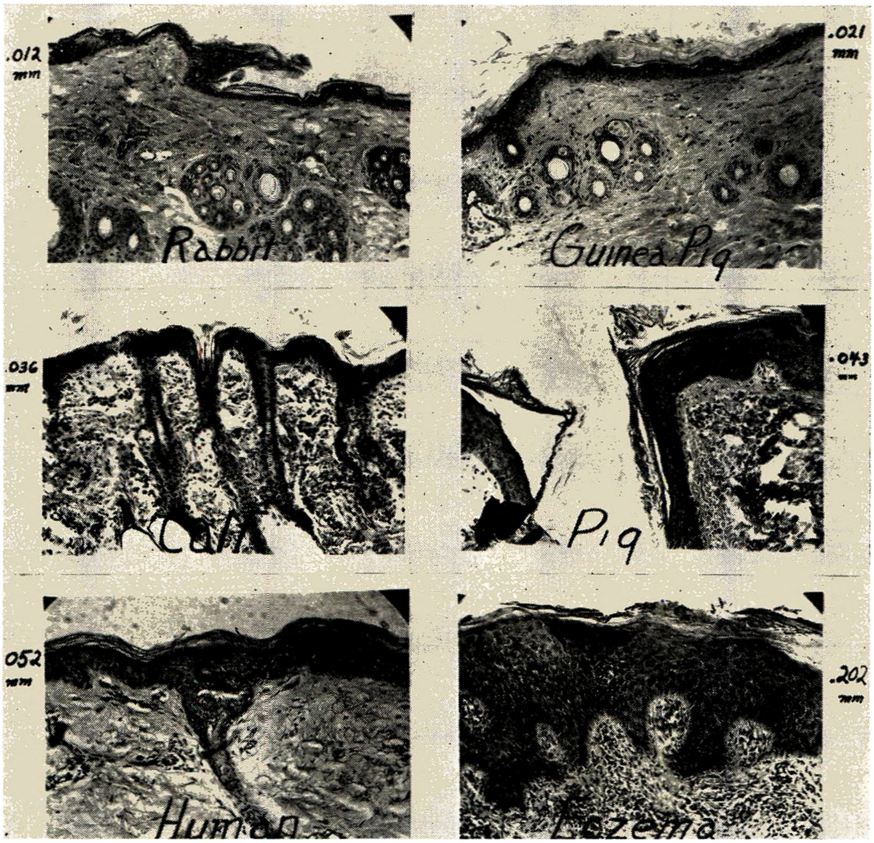


Figure 2.—Skins of Animals. (Credit: H. J. Spoor, *Proc. Sci. Sect. Toilet Goods Assoc. No. 36*, 20 (1961).)

the epidermis does respond quickly to irritation. The section labeled "eczema" shows a maximum thickness reached by one epidermis before frank eczematization and exfoliation occurred. Seborrheic eczema could appear this way.

Another important factor influencing dandruff formation is the amount and type of sebum secreted. This emollient, when properly dispersed, can smooth and flatten out dry horny skin layers without affecting normal desquamation. However, should sebum become excessive or accumulate at the pore openings the desquamating scale may adhere in visible oily masses. Dandruff is most apparent on the scalp or other hairy areas because sebaceous glands surround hair follicles and the sebum is discharged upon the hair shaft as a lubricant and protective coating. Sebaceous secretions also furnish lubrication to the non-hairy skin, but here the emollient is discharged directly upon the skin surface through pore openings that are associated with lanugo or primitive hairs. The oil is dispersed more broadly than in the hairy areas. The amount of sebum is influenced by the individual's genetic pattern, nutritional state and endocrine balance. Usually dark skinned individuals secrete more sebum than do those with lighter skins, the younger adult has more skin oil than the older and the male more than the female. Nutritionally, variation in the intake of fats or their impaired metabolism due to deficiency or improper utilization of certain vitamins may alter sebum flow. Specific foods, drugs or allergens may aggravate oil excess. Steroid hormones influence the development and function of the sebaceous glands. Generally, testosterone or the male type hormones promote both the growth and excessive function of the oil glands, while the estrogens or the female type hormones counteract both these actions. Work with the pituitary and the adrenal cortical hormones shows that these, too may have direct action upon sebaceous glands. The oil-rich, scale-laden scalp furnishes an excellent culture medium for many types of bacteria, some of which may bear causal relationship to the extension of simple dandruff to clinical seborrhea (2).

I have found it increasingly difficult dermatologically to separate simple scalp dandruff from the rest of the seborrheic diatheses, so to my mind, antidandruff agents must have therapeutic value. I think that:

1. The seborrheic state, in all its facets, stems from a common cause.
2. Some disturbances of the sebaceous secretion and epithelial keratinization are involved.
3. These disturbances may well be of allergic nature.
4. They are always found associated with bacterial and yeast invasion.

Furthermore, legally, if not medically, one of these yeast groups, Pityrosporum ovale, has been considered a causative agent of infectious dandruff. Accordingly, any product making antidandruff claims must be capable of destroying both these yeasts and certain associated bacteria (Staphylococci). Obviously, no product should be considered of medical value until it has proved itself to be clinically effective in seborrheic individuals.

In past years a useful yardstick for measuring the effectiveness of antidandruff agents has been their effect on yeast like organisms cultured from the scalp. The "bottle bacilli" are difficult to cultivate artificially unless the acid, oily, partially anaerobic conditions under which they grow naturally are simulated. Unfortunately, it has been our observation that even though the organism certainly occurs on the majority of normal male and many female scalps, it is not associated with seborrhea and dandruff in high enough frequency to establish causal relationship. The most apparent correlation we could find after studying 100 young men was that an increase in adherent scale was associated with an increased frequency of positive culture but that many of the subjects with no evidence of hair loss, dandruff or seborrhea showed positive cultures for the organism (3).

A broader bacteriological base than just Pityrosporum ovale cultures was needed. Therefore, we studied the scalp bacteriology of a group of patients with seborrhea to determine flora patterns. All individuals had routine scalp cultures made on three media: brain-heart, Sabouraud's maltose and Benham's wort agar. The dominant organisms were Staphylococcus aureus, Staphylococcus albus and Pityrosporum ovale yeasts. All individuals harbored the Staphylococci but there was an apparent male dominance of yeast infection susceptibility (2).

The next approach to the problem of evaluating antidandruff agents was to screen materials in the laboratory for their potency against the particular bacteria and yeasts isolated from seborrheic individuals. Typical results obtained on a laboratory screening are shown in Table I. Here measurements against the Staphylococci and several of the Pityrosporum groups are shown. The behavior of chlorinated phenols, quaternary ammonium compounds and anionic detergents indicates their failure to

Table I—Laboratory Comparison of Germicidal Agents Tested Against Organisms Associated with Seborrhea

		Cup Plate Assay—Inhibition Zones, mm.				
				Pityrosporum ovale		
Agent	Concentration	Staph. aureus	Staph. albus	Type 1	Type 2	Type 4
Hexachlorophene (G-11)	0.35% lotion	24	30	Slight	0	0
Quaternary ammonium type	0.1% aqueous	30	32	23	Slight	Slight
Sodium alkyl sulfate (Duponol)	1.0% aqueous	22	17	Slight	Slight	Slight
Merthiolate	0.01% aqueous	23	20	25	...	...
Phenyl mercuric acetate	0.01% aqueous	23	26	39	...	...
Sodium sulfacetamide (Sebizon)	10% aqueous	Slight	20	28	Slight	Slight
Actamer type compound	1.0% glycol	38	42	52	33	26
Selenium sulfide (Selsun)	2.5% aqueous susp.	34	27	38	37	30
Polysulfide compound	3% alcohol	56	41	40	43	35

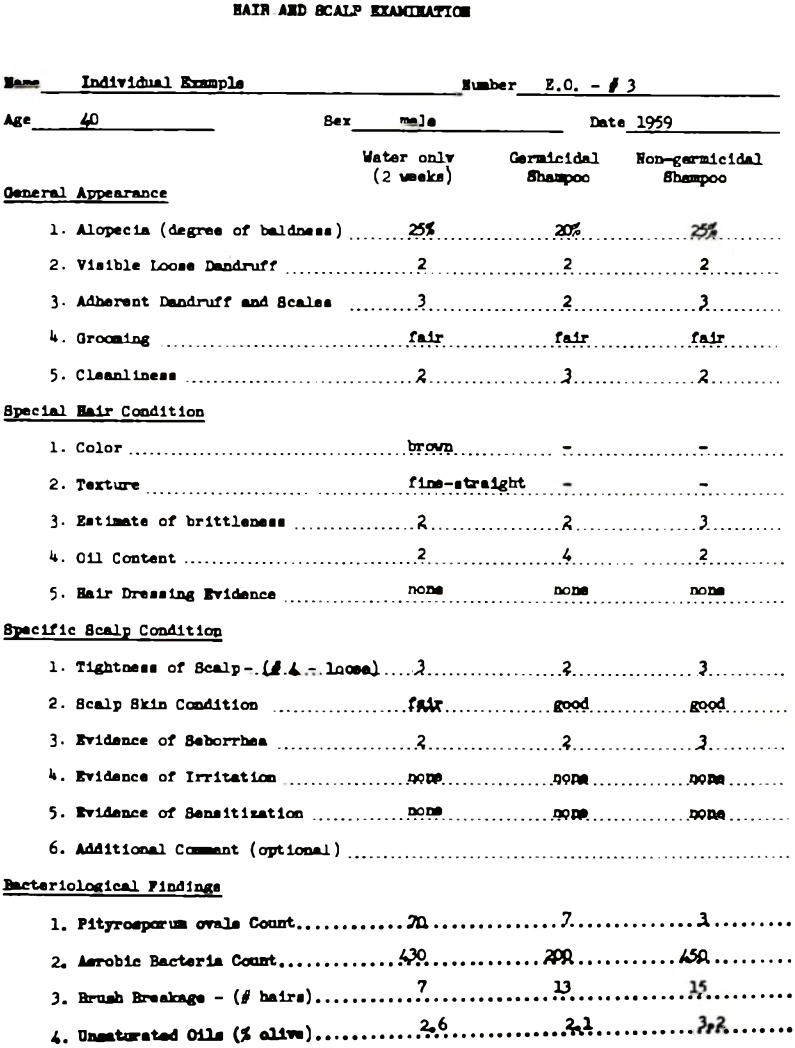
control adequately the Pityrosporum ovale. To obtain the broadest spectrum either a mercurial or some type of sulphur containing compound is desirable. This, of course, confirms clinical experience, because ammoniated mercury or sulphur preparations have been used widely for many years.

During the past two years we have found it worthwhile to culture the specimens taken from seborrheic scalps on an anaerobic bacteriological medium in addition to the other media. We have not yet screened antidandruff agents against the anaerobic Staphylococcus that dominates this medium.

In the past, we have relied heavily upon such laboratory comparisons. Laboratory study will separate the more effective antidandruff agent from the less, but it cannot guarantee clinical value. We have developed a panel type of comparative use test, wherein under controlled conditions subjects may compare clinically several products. This panel type of study has been sufficiently selective to differentiate between antidandruff agents that could not be separated by laboratory criteria. Normal male subjects are used because first, their short hair permits greater efficiency in scalp and hair sampling and secondly, the measurable factors found in dandruff conditions are more apparent in men. Details of this method have been published together with some general examples of the results (4), but further extensions of the work with some specific data on antidandruff formulations will now be given. Comparative data are collected and quantitated during clinical examinations of the subjects at definite periods after use of the products. During the test periods (weeks), the test products are randomized to minimize the effects of uncontrollable factors such as temperature, humidity and dust in the environment. A standard method of evaluation has been evolved through experience. The examination measures the more general hair and scalp features, such as alopecia, visible loose dandruff, adherent dandruff and scale, grooming and cleanliness, as well as specific hair factors, namely, color, texture, brittleness, oil content and others. Scalp skin conditions, e.g., tightness, seborrhea, irritation or induced sensitization, are recorded. Laboratory work on bacterial flora, hair fragility and oil content are also completed. Quantitation is obtained by grading all observations numerically in terms of 1 to 4. Real numbers assigned to grade clinical observations make subsequent data comparison possible.

Table II gives comparative data obtained for an individual subject. Shown are the examination values found after a control period during which no shampoo was used, after a similar two week trial period during which a germicidal shampoo was used, then again after a period during which a nongermicidal shampoo was used. It may be noted that use of the shampoo containing 1 % G-11 increased the apparent oiliness of the hair,

Table II—Hair and Scalp Examinations (Individual Example)



HAIR AND SCALP EXAMINATION

Name Individual Example Number E.O. - # 3

Age 40 Sex male Date 1959

	Water only (2 weeks)	Germicidal Shampoo	Non-germicidal Shampoo
General Appearance			
1. Alopecia (degree of baldness)	25%	20%	25%
2. Visible Loose Dandruff	2	2	2
3. Adherent Dandruff and Scales	3	2	3
4. Grooming	fair	fair	fair
5. Cleanliness	2	3	2
Special Hair Condition			
1. Color	brown	-	-
2. Texture	fine-straight	-	-
3. Estimate of brittleness	2	2	3
4. Oil Content	2	4	2
5. Hair Dressing Evidence	none	none	none
Specific Scalp Condition			
1. Tightness of Scalp - (# 4 - loose)	3	2	3
2. Scalp Skin Condition	fair	good	good
3. Evidence of Seborrhea	2	2	3
4. Evidence of Irritation	none	none	none
5. Evidence of Sensitization	none	none	none
6. Additional Comment (optional)			
Bacteriological Findings			
1. Pityrosporum ovale Count	20	7	3
2. Aerobic Bacteria Count	430	200	450
3. Brush Breakage - (# hairs)	7	13	15
4. Unsaturated Oils (% olive)	2.6	2.1	3.2

although this was not confirmed in this individual instance by an increase in the measured unsaturated oil. Both shampoos increased breakage over that found following the water controls. Both shampoos reduced the Pityrosporum ovale count, but only the G-11 containing shampoo reduced the total aerobic bacteria count.

To help equalize the effects of individual variation, the data from an entire subject panel may be averaged for comparison. In the next table (Table III) the averaged values from 11 subjects are compared. Shown are values after water controls taken one year apart, soap shampoos without and with G-11, cream shampoo with G-11 and an Actamer containing shampoo. There is also a data series obtained after the same subjects had used alcoholic hair dressing antidandruff preparations, rather than the shampoos. The preparations were with and without antibacterial additives, and the antibacterial preparations were with and without added sulfur compounds. The preparation with no added antibacterial agent was used by the subjects for two two-week periods spaced one month apart.

TABLE III—COMPARISON OF ANTIDANDRUFF AGENTS BY QUANTITATED CLINICAL CRITERIA

	Average Values for Subject Panel—(Graded 1 to 4)									
							Alcoholic Hair Dressings			
			Shampoos				Antibacterial		Without Antibacterial Agent	
	Water Controls #1	#2	Without G-11	G-11 Soap	G-11 Cream	Actamer	With Sulfur	Without Sulfur	#1	#2
					Clinical Criterion					
Loose dandruff	2.1	2.1	1.3	1.4	1.1	1.5	2.1	2.2	1.4	1.4
Adherent scale	2.0	2.5	1.7	1.6	1.6	2.0	2.2	2.2	1.5	1.6
Hair brittleness	1.6	1.8	1.8	1.6	1.7	1.4	...	...	1.9	2.4
Hair oiliness	2.4	2.4	2.1	2.3	2.2	2.0	...	...	2.4	2.2
Scalp cleanliness	2.2	2.5	3.1	3.2	3.0	2.4	...	...	1.3	1.4
Scalp looseness	1.9	2.4	2.1	1.9	1.9	2.2	...	...	2.2	1.8
Scalp redness	1.9	2.1	1.5	1.4	1.1	1.5	1.9	1.6	1.0	1.1
					Laboratory Criterion					
Pityrosporum, subjects, %	36	54	10	20	10	10	18	36	47	40
Aerobic bacteria count	545	496	134	121	+	+	+	+	++	++
Brush breakage, hair#	15	16	11	10	8.6	7.7	11	8.2	11	11
Unsat. oils, olive, %	3.2	2.1	2.7	4.5	3.3	2.3	2.1	2.9	4.4	3.9

The tabulated data indicates that all shampoos, with the possible exception of that containing Actamer, reduced loose and adherent dandruff. The antibacterial hair dressing material, on the other hand, did not reduce dandruff, while the more bland hair dressing did. The observed findings on brittleness were equivocal. Hair oiliness was reduced by the shampoos, not by the alcoholic hair dressings. Shampooing added cleanliness, again excepting the Actamer-containing product. The hair dressings left the scalp less clean. No meaningful changes could be determined in scalp looseness, while scalp redness was decreased, following use of the shampoos and the bland hair dressing material. The Pityrosporum ovale culture data was quite clear cut. Shampoos reduced the percentage of individuals harboring the yeast; hair dressing materials did not, except where added sulfur was present. Aerobic bacteria counts behaved as expected and were reduced after use of an antibacterial containing preparation. Hair breakage was least after use of the cream shampoo and the sulfur containing hair dressing material. Unsaturated oils rose appreciably after use of the G-11 soap shampoo and the bland hair dressing material.

Tabulated data of the type shown often cannot withstand the statistician's onslaught, but they are meaningful to the clinician when they reflect observed individual trends. If the majority of subjects respond in a particular manner, and an arithmetic average of all subjects confirms the majority trend, the change is probably real.

Despite the apparent requirement that an antidandruff formulation be an effective cleansing agent and have demonstrable antibacterial powers, it is often found in practice that such products are not the most satisfactory for treating seborrheic individuals. Preparations such as the bland hair dressing shown in the preceding table are often most satisfactory therapeutically. These questions arise; is all dandruff the same and what type of individual has a susceptibility to this seborrheic state? It is known that Seborrhea capitis may be just an early clinical sign of some other skin conditions or it may remain an entity in its own right. Not known is the percentage of individuals with seborrhea that go on to develop other skin conditions or with what frequency other diseases have an associated dandruff condition. Such knowledge might help explain why antidandruff formulations are not uniformly effective.

During the past few years, I have taken particular note of the patients with dermatoses possibly related to Seborrhea capitis who have come to my office for treatment and have now made an analysis of these records. In addition to the seborrheic diatheses shown in Fig. 1, one finds dandruff associated with baldness, acne vulgaris, psoriasis, and infantile ezcema (Fig. 3). I have excluded from my study the minor number of hair loss cases whose cause can be determined and for which therapy is often effective. For example, these cases are those of alopecia due to psychic or physical trauma (a. areata, a. totalis), systemic disease (Lupus erythematosis) and specific infection (Tinea capitis). However, by far the major number of alopecia cases are those of male and female pattern baldness, and, for treatment of these, little can be done. Most of us associate dandruff with acne vulgaris because it, too, is a disease of the pilo-sebaceous system. Psoriasis is probably a hereditary disturbance in fat metabolism, yet we have a condition known as seborrheic psoriasis, and psoriatic scalp lesions are of very frequent occurrence. Infantile eczema, on the other hand, is almost entirely of allergic origin, yet it very frequently first presents itself as "cradle cap."

An analysis of data taken from my office records of appropriate patients with these particular dermatoses seen during 1960 and 1961 is given in Table IV. There were 90 individuals with male or female pattern alopecia. Eighty-three % of these patients had dandruff, the men even more than the women. There were 94 individuals with acne, but despite the fact that this is a pilo-sebaceous disorder, only 42 % had dandruff. Similarly, of the 15 cases of psoriasis, only 46 % had dandruff.

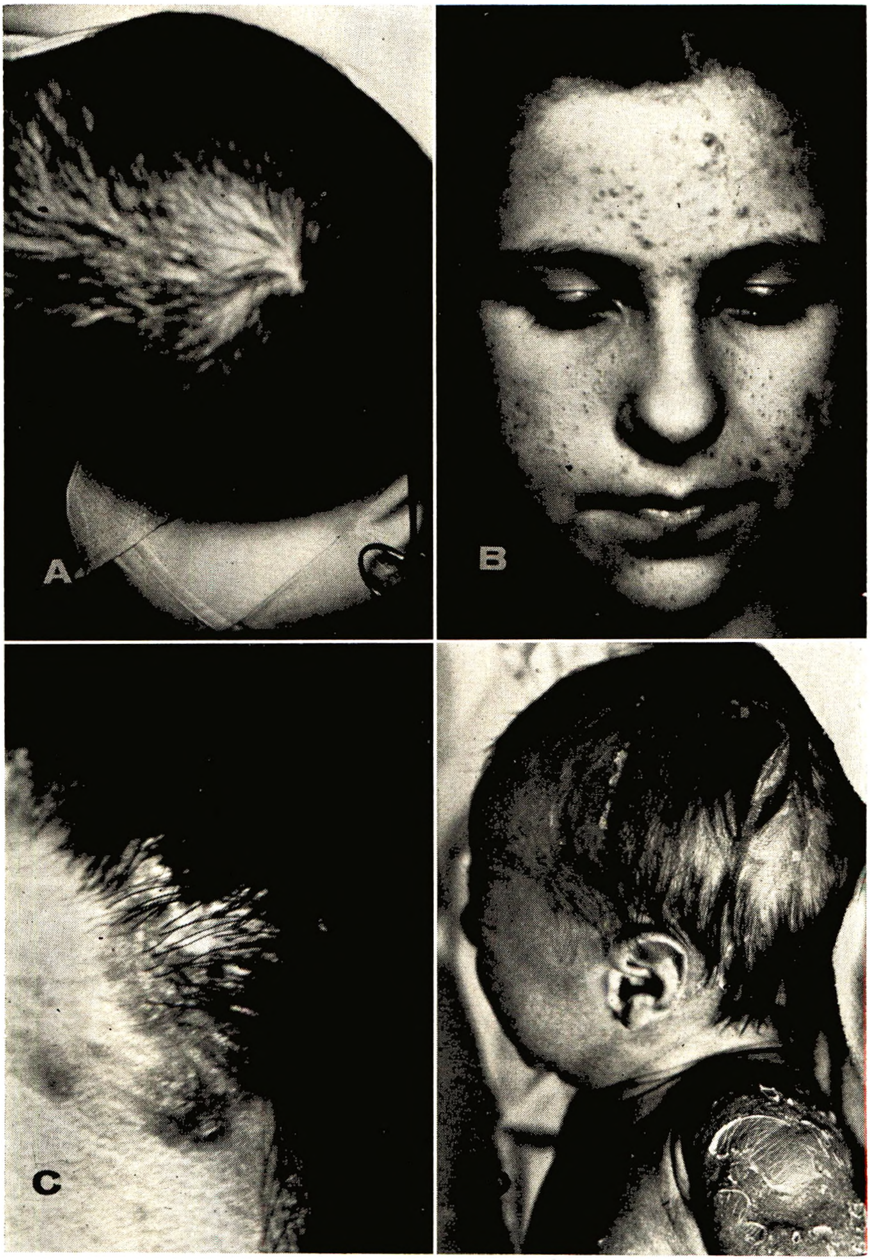


Figure 3.—Dermatoses related to seborrhea (dandruff). (A) alopecia. (B) acne. (C) psoriasis. (D) infantile eçzema.

Eight infants with facial or body eczema attributable to a food allergy all had dandruff. Finally, there were 16 adults with severe seborrhea who had no alopecia nor clinical sign of any other dermatologic disease. There were a total of 207 patients in the study group: 146 (70%) had dandruff, yet only 16 (11%) of these had only scalp seborrhea and no other skin condition.

I must conclude that dandruff is a very common sign that suggests an impending abnormal behavior of the skin or its appendages. The rationales for therapeutic use of antidandruff agents is therefore sound. A formulation should clean the hair, free the scalp of adherent debris and regulate the amount of residual scale and oil to retain healthful scalp conditions. Antibacterial properties either inherent in the formulation or as added germicidal agents are helpful. Mild keratoplastic or keratolytic action may help regulate epidermal sloughing.

Table IV—Association Between Seborrhea (Dandruff) and Related Dermatoses (Private Practice—N. Y. City—1960 and 1961)

	Total	Male	Female
Alopecia			
With seborrhea	75	46	29
Without seborrhea	15	6	9
Acne			
With seborrhea	40	11	29
Without seborrhea	54	11	43
Psoriasis			
With seborrhea	7	4	3
Without seborrhea	8	5	3
Seborrhea Alone			
Adults without alopecia	16	7	9
Infants with food eczema	8	4	4

There have been a number of effective antibacterial agents developed, some of which compare favorably with the therapeutic standard, the selenium sulfide formulation. Further progress will come through use of antiallergens, similar in action to the topically applied corticosteroids. Not only analogs of hydrocortisone but also the sex hormones and their derivatives may prove useful. Topically applied vitamins and enzyme inhibitors may influence sebum flow. There is still room for antidandruff formulation improvement, but developmental study of each new ingredient must follow conventional design and be scrutinized on all facets of the dandruff disease process.

(Received September 20, 1962)

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PREDICTION OF THE RHEOLOGIC AGING OF COSMETIC LOTIONS

John H. Wood, Ph.D., and Gregory Catacalos, B.S.*

Presented September 20, 1962, Seminar, New York City

In studying the aging of cosmetic lotions after preparation, the cosmetic formulator often finds himself on the horns of a major dilemma: how to predict from short periods of time what will happen during the normally accepted shelf life. The normal rule of the chemist for determining shelf life is to set samples at a series of temperatures and to evaluate a classic rate constant for the reaction. The formulator is beset by the problem that his creations frequently have extremely complex behavior when stored at various elevated temperatures, for example, the classic heat hardening of many soap-containing formulations. In such a case, from the phase rule viewpoint, his formula is simply moving at reasonable rates into the ever present gel regions characteristic of long chain compounds in water. However, at lower temperatures this often never happens, for the rates are so much slower.

Alternately, the elevated temperatures lead to the melting of one or more components and hence a complete change in the nature of the formulation. Often high temperatures maintain an impurity in solution so that the high temperature forms remain satisfactory when those stored at lower temperatures soon become cosmetically unelegant. Thus, though the formulator uses accelerated testing as a guide, he feels forced to rely ultimately on room temperature behavior. Certainly the standard Arrhenius relation seldom is of use to him, and his systems rarely obey conventional kinetics.

The formulator usually uses observing periods of roughly doubled time intervals—thus 1, 2, 4, 7 and 14 days; 1, 3, 6 and 12 months. Experience has taught him that in these time intervals he may expect to see sufficient change to justify the observations. More frequent observation is usually impossible because of the demands on his time.

However, the normal frame of reference is based on the linear time scale; and it is often said that the changes are leveling off. That is, there is an asymptotic approach to a limit, since as much change occurs in going from one to three months as occurred in one to three days.

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Several years ago, as a matter of convenience, one of us (G. C.) began using logarithmic plots as a convenient compacting device to consolidate rheological data from days to months onto a reasonable plot that would give equal weight to all observations. It was soon evident that for many viscosity plots a reasonably good straight line was obtained for a plot of the logarithm of viscosity against logarithm of time, using any suitable units. The first tentative mention of this was over a year ago (1). Since that time, we have sought to examine the possible generalization of such a relationship and the underlying logarithmic time dependency in order to assess the reliability of the generalization and hence in turn the significance of any departure from such a behavior.

Of course, empirical line straightening and data compaction are often obtained by the use of square root or higher roots of the variable. To obtain a crude linearity between a root plot and a logarithmic one, it is necessary to use a root power at least 0.5 greater than the number of logarithmic decades considered. Therefore, for four or more time decades the power root dependency on time is theoretically not probable.

Occurrence of the Logarithm time Dependency

First it is well to examine how significant is the aging property dependence on logarithm of time, as evidenced from published literature. The examples chosen are not intended to be complete but rather were chosen because they were known to the authors as cases where a logarithmic time dependency was found empirically necessary.

Two examples of emulsion stability were available. The first by Menczel *et al.* (2) clearly demonstrated by a colormetric technique that the logarithm of the per cent separation of internal phase was directly related to the logarithm of time for time periods from minutes to several days. These authors suggested an emulsion stability grading system based on this relationship. A similar relationship was found by Christian (3) for the creaming rates of various emulsions using radio isotopic measurements for the ratio present at the top and the bottom of a cylinder.

We have recently reported (4) that the viscosity build-up by hydration of Veegum®*, a bentonite type clay, regardless of the temperature of storage, is related to the age of the suspension by a linear log-viscosity log-time relationship, holding over a time range of hours to months.

In a recent paper, Levy (5) reports the build-up with time of the various rheologic parameters useful to characterizing a bentonite gel, dynamic and static yield value, thixotropic area, and plastic viscosity. As may be seen from Fig. 1, these properties are well characterized when plotted on a log-property log-time plot by a straight line relation.

Chong (6) showed that the growth of anti-thixotropy for a magnesia

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* Veegum is a trade name of the R. T. Vanderbilt Co., Inc.

magma was related to the logarithm of time. Subsequently he found (7) that a better linear relation held for a plot of the logarithm of the growth against logarithm of time.

In another recent paper, Levy (8) has studied recovery rates from disturbances in strongly thixotropic bentonite gels. He reported that the recovery strength of the gel was related to the logarithm of time in a manner analogous to that noted by Chong (6). Actually, in the range of recoveries observed by him, the logarithm of recovery would fit the data quite as well and for our purposes may therefore be assumed to hold.

In the field of metallurgy (9), it has long been an empirical fact that many annealing processes are well depicted by the log-log plot against time.

Similarly the exchange reaction of HCl gas on sodium chloride (10) follows this relationship. Other experiments (11) studying irradiation defects have equated a linear function of per cent change to the logarithm of time, while a group (12) studying the polymorphic transition in tin utilized a double log function of the fraction transformed as the variable against the logarithm of time.

THEORETICAL BASIS FOR THE RELATIONSHIP

Avrami (13) has examined the general kinetics of phase transformation in solid systems and has shown that, for conditions of isolated nucleation, a proportionality can exist between transformed volume and a power of the elapsed time. If it is assumed that we are dealing in systems where such isolated nucleation of changes is diffusion inhibited, then thick cosmetic lotions should, in a first approximation, obey this proportionality. If it is then assumed that the extensive property (P) under examination is directly related to the degree of transformation that occurred in time (t),then

$$P = a\,t^{b}$$

$$\text{and } \log P = b \log t + c$$

where a, b and c are constants of the systems to be evaluated empirically.

For cosmetic lotions, diffusion controlled and isolated nucleation reactions are possible in many cases. Certainly, the diffusion control of the solid state might be expected to be less rigorously obeyed for a viscous semi-heterogeneous mixture than for the solid, and indeed this is the general case in the cosmetic lotions. However, the resultant behavior should be expected to be some compromise between the normal kinetics of the homogeneous system which involve a linear function of time and the limiting solid-state type dependency on the logarithm of time.

APPLICATION TO COSMETIC LOTIONS

In Fig. 2 are shown logarithmic viscosity-time plots for several different systems. The solid lines represent heat emulsified solid fat systems, the dotted line a hand lotion, and the dashed lines antiperspirant lotion formu-

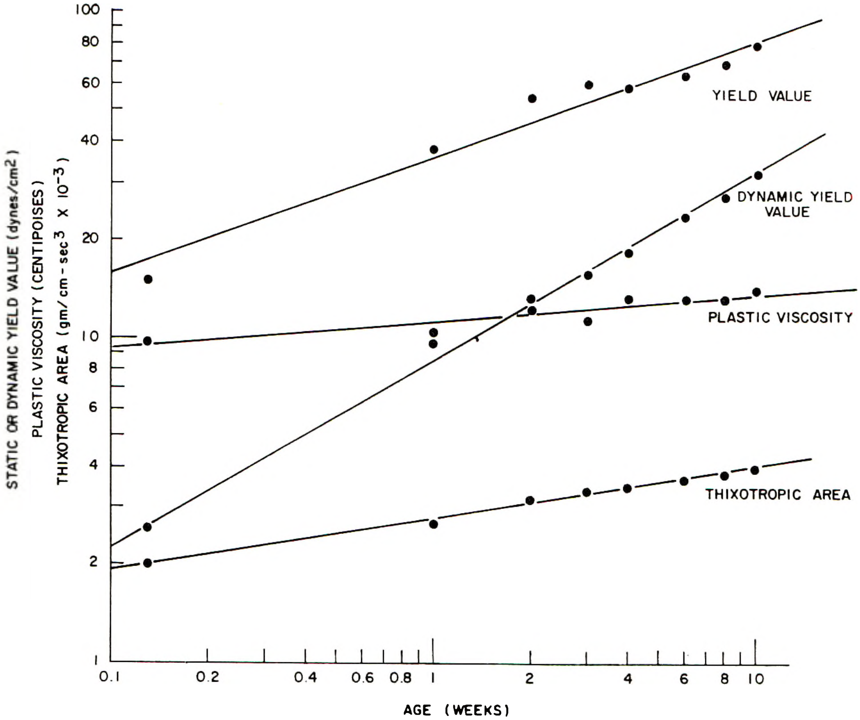

Figure 1.—Data of Levy and Rutowski (5) replotted on logarithmic basis, to show the build-up of the rheologic parameters of bentonite with time.

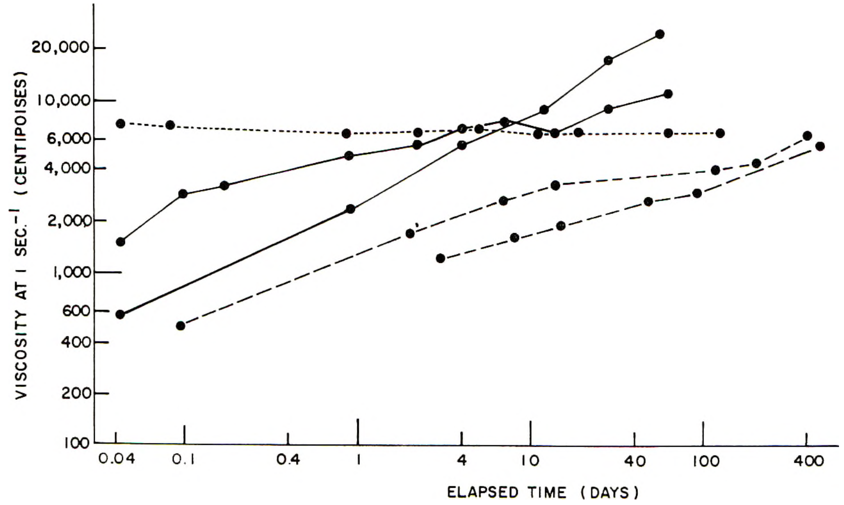

Figure 2.—Some aging curves of cosmetic lotions. (- - - - - cosmetic hand lotion, ——— "solidified" fat systems from a hot emulsion, — — — antiperspirant lotions).

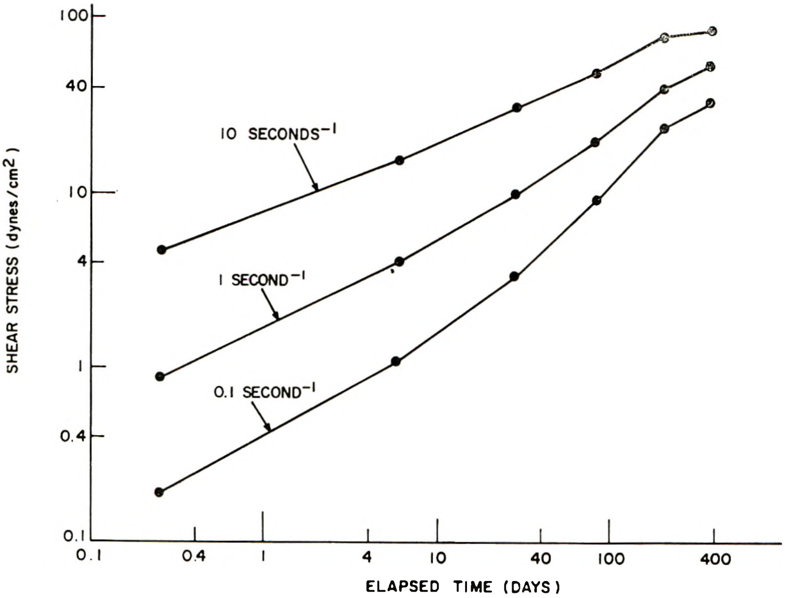

Figure 3.—The change in shear stress with time for three different shear rates for an antiperspirant lotion.

lations. In each case, the linearity is quite satisfactory. In this example, we have arbitrarily used the viscosity at one second^{-1} shear rate as read graphically from a rheogram. Other choices are open, and in Fig. 3, for one lotion, aging curves at three different shear rates are shown for the actual shear stress measurement. It is apparent from these curves that the

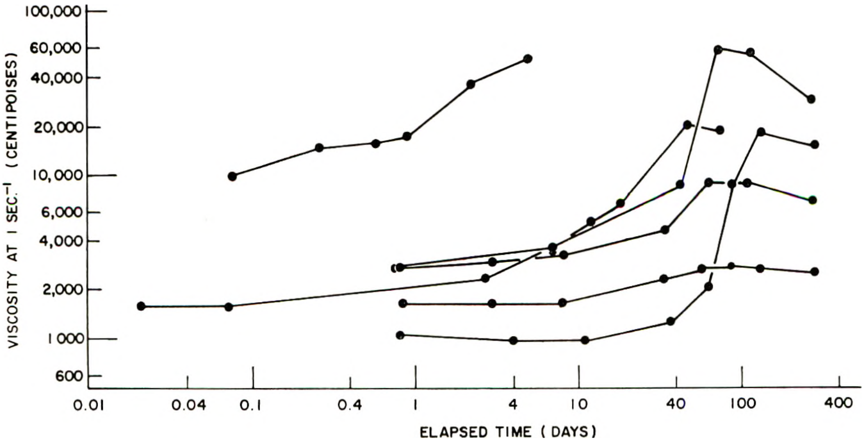

Figure 4.—Aging curves for various formulation and process variants of a lotion subject to age hardening.

low shear yield value term is building at a faster rate than the plastic viscosity. Thus a series of lines may summarize for a lotion any desired shear properties.

In some cases, after an initial period of linearity, the slope of the line shows an increase with time (see Figs. 4 and 5). Such an increase is frequently followed by a marked drop. At this time we are inclined when using these plots to consider that as long as the linear holds, regardless of the slope, the lotion or paste is behaving normally. Of course, it is ideal if the aging curve is flat, but this is seldom seen. If a tendency toward marked upward curving becomes apparent after some variable induction period, we consider that excessive "hardening" is possible. This abnormal increase often is the forerunner of an eventual drop in viscosity signifying phase separation.

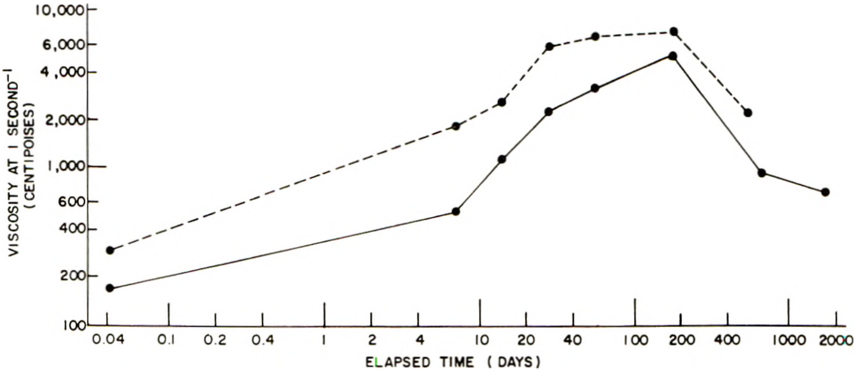

Figure 5.—Effect of delayed filling on the aging viscosity of a lotion. (— — — filled the same day as making; ——— filled the following day.)

Implications of the Use of Log Time Plots

First it is of interest to note that the average time-doubling scale so frequently used for cosmetic lotion observation is close to the logarithm time choice favored here.

Secondly, the logarithmic scale of viscosity has been shown by Fryklöf (14) to be directly related to a linear scale of subjective or ocular judgment of consistency.

What in practice is gained by the logarithm plot of property and time? When there exists a simple and essentially linear relation, and this is reasonably common, there are two major advantages which can be of great value to a stability program. The first is that as long as a reasonably linear relation holds there is considerable confidence that aging is not inducing any unanticipated complications. The other, and possibly the most important, is the tentative long range prediction available from early measurements, especially when anchored by the normally more rapidly changing values of the very early hours after formulation. Usually, because the changes are so rapid in the first one or two days, these observations are often very limited or more commonly completely ignored. We prefer to get several points in this time region, preferably from as early as one-half to one hour after formulation. In this manner we have established the projection of the line through one or more decades of time (in days) without having to wait a week or more to pass. At any time interval, projection to at least double that time is very safe, and frequently several mutiples can be used with discretion. In general we have always utilized the time interval of days in our plot. Thus at two to three days we feel that we can project in a rapidly changing system to ten days. By one hundred days we feel one year's prediction to be quite safe.

Now, unfortunately, the linearity is not always there. There are, of course, only two directions for deviations. If the curves deviate downward, that is, the suspension thins out, then, of course, stability is dubious and it requires no great refinement of data to realize this. If the deviation is upward, then the suspension is thickening at a rate that can only lead to trouble. In the extreme, we have found such cases to be linear with time, and hence the reaction is not diffusion controlled. In such cases the more usual kinetics govern. Such systems often involve hydrolysis of one or more components or the direct reaction between two components. Obviously such reactions are more likely to proceed rapidly in the more fluid systems.

Cosmetic Lotion Process Study

The logarithmic plot serves as an excellent tool to compare process variables during an aging investigation. Thus in Fig. 4 are seen a few of the various formulations and process attempts to prepare a lotion of acceptable rheological behavior. It is quite obvious that such a graph clearly permits comparisons between formulations in a manner that no other plot can do because of the range of values involved.

Similarly in Fig. 5 we see the effect of delayed filling on a cosmetic lotion subject to separation. It is striking that the delayed shear effects, so pronounced during the initial aging period of the sample (15), can continue for so long.

In Fig. 6 are seen the effects on one batch of a cosmetic lotion of withdrawing a portion before the temperature had been dropped completely in the finishing step. Both portions were each filled the same day and after one-day's storage. The unfilled and the same-day-fill portions were indistinguishable for both finishing conditions throughout the duration of the study. However, the aging patterns for the two finishing temperatures are quite different. For both samples the effect of delayed fill on rheology was quite pronounced.

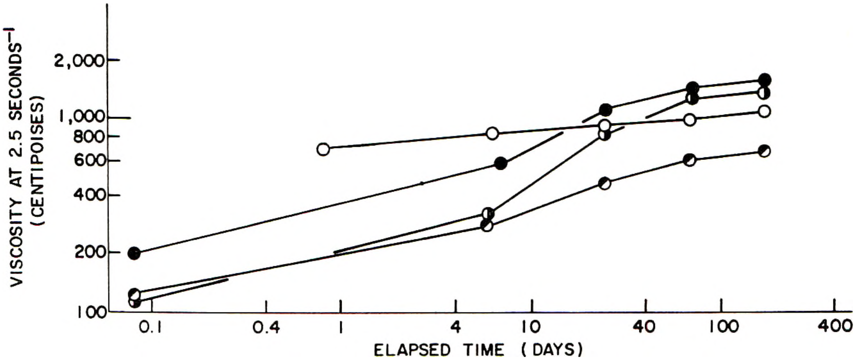

Figure 6.—Effect of two finishing temperatures and delayed fill on the rheologic aging of one batch of a lotion. ○—higher temperature, unfilled and same day filling; ◐—higher temperature, filled second day; ●—lower temperature, unfilled and same day filling; ◑—lower temperature, filled second day.

In Fig. 7 are shown a few of the results obtained for a lotion containing triethanolamine. The upper, flat, line represents the use of straight 98% "pure" triethanolamine. The lower, steepest, curve is for 25% of this and 75% of the technical grade. The intermediate curve is for a 50–50 mixture. Straight technical grade material yields a line close to the 50–50 one but slightly lower. The curve for 75% "pure" was intermediate between the 100 and the 50% mixtures. Variants on this formula minimized this difference. As before, the logarithmic plot permits a compacted evaluation of the whole aging pattern.

Effect of Temperature on Aging

In our work (4), a clean-cut dependency of the logarithm of viscosity on the reciprocal of the absolute temperature was noted for the setting up of a Veegum suspension. This is typical of the behavior in a system where rigid kinetics dominate throughout. Similar results are also classic in the metallurgy field.

Figure 8 shows the results of storing a cosmetic lotion at several temperatures for a prolonged period. It is immediately apparent that with increasing temperature other phenomena enter, and there is no continuous relation between property and temperature. Indeed, temperature inversion, as here, is the frequent rule. Often, and probably in this case, one of the other phenomena is melting of one or more of the components of the lotion.

Except in rare cases, we do not find that we can anticipate much in rheologic behavior from accelerating aging. One important exception to this, however, should be noted—upward deviations generally occur much earlier as the temperature is raised, and so the use of the elevated temperature can be a warning of probably eventual similar behavior at room temperature.

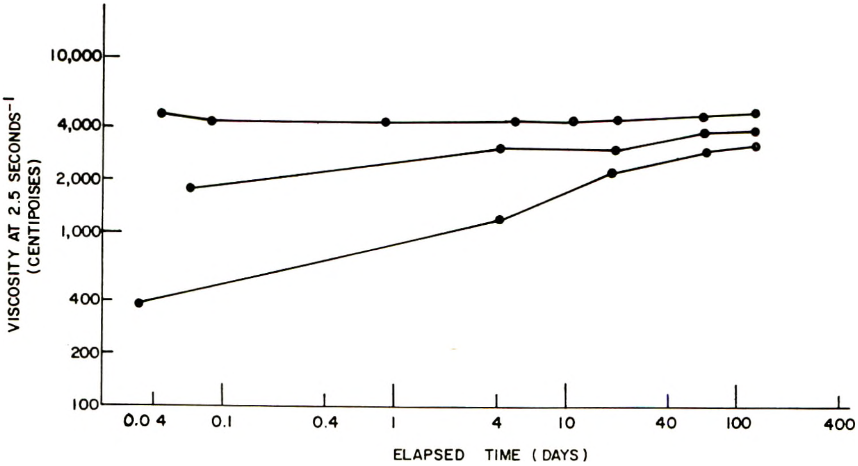

Figure 7.—Aging of a lotion prepared with different ratios of 98% and of technical grade triethanolamine.

It is intended later by the study of the equation of flow to attempt to derive parameters from such equations that will recognize the likelihood of this type of behavior before it is clearly established. Our first efforts in this regard are promising, but considerably more work will be necessary before it can be clearly established.

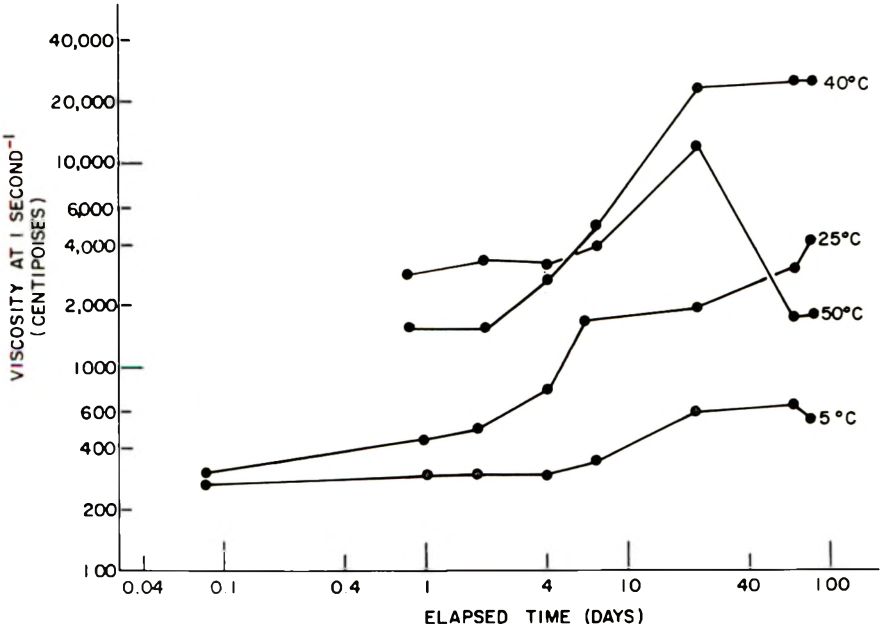

Figure 8.—Effect of temperature on the aging properties of an antiperspirant formulation.

SUMMARY

The use of plots of the logarithm of time with the logarithm of the various extensive properties examined in an aging program is suggested as the best way to evaluate the normality of the aging process.

Deviations from linearity may be used as guides in anticipation of untoward behavior.

The linearity of the logarithmic plot of time and extensive property permits safe prediction of properties for two to three age periods beyond the last observation.

Its utilization in the course of process and formulation studies permits a compacting of considerable data for comparison into one or more convenient graphs.

(Received September 18, 1962)

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These two volumes have been completely updated to include the many new materials developed in the last ten years. Each infrared spectrogram includes the chemical or trade name, source, scanning from 2.0 to 15 microns, type of cell or special method used, index number and often the instrument used in obtaining the results.

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This reference library is a great help to infrared technicians in making available the transmission spectra of a wide variety of materials encountered in cosmetic practice without the manual effort in doing the work. At a cost of about 50 cents per spectrogram, you cannot do it for yourself so inexpensively.

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This reviewer has found the material of infinite practical value, as you will if you do infrared analysis.

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AUTOXIDATION AND ANTIOXIDANTS, Vol. I, by W. O. Lundberg. Interscience Publishers, Div. John Wiley & Sons, New York 1, N. Y. 1961. 450 pages, indexed and illustrated. Price $15.50.

This volume consists of ten chapters contributed by a group of 12 authors, each a specialist in a specific field of autoxidation and antioxidation chemistry.

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The analytical chapter includes both discussions and analytical procedures for the determination of peroxides, oxirane compounds hydroxyl, carbonyl and ether radicals, unsaturation, and the use of spectrophotometry in this field.

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This book is well written, arranged and indexed.—JAMES H. BAKER, Gar-Baker Laboratories, Inc.

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Reservation deposit	25.00‖	25.00‖

* The package deal includes room from Sunday evening June 21, through breakfast Saturday, June 27; all meals at Columbia; banquet and cocktail party, and all official functions and meetings in connection with the seminars. The "Package Deals" are for parties of three or four in a suite of two rooms (each with two beds) and one bath. Separate keys are provided for each room. The bath is off the hallway entrance to the two rooms. There is a telephone in this hallway serving the two rooms. All rooms are in "New Hall" which is adjacent to Ferns Booth Auditorium. The cost per person is the same whether four or three people occupy the suite. If only two people occupy it, the cost of the "Package" will be $10 more per person. Entire suites will be reserved only for two or more people. What few "singles" are available must be held for invited speakers.

† Meetings, etc., includes all official functions in connection with the seminars, banquets and cocktail party; also luncheons at Columbia following each seminar session.

‡ The Package Deal and Meetings are free to members in good standing prior to June 1, 1963, of societies affiliated with the IFSCC other than U.S.A. members, provided reservations are made before June, 1963. After June, 1963, they will only be accepted provided funds are still available for this purpose. Early registrants will be certain of receiving this benefit which applies to the actual member only—not his family. All overseas registrants are expected to pay a deposit of $25 each when making reservations. This deposit, which will be returned when they arrive at the Congress in 1964, is necessary to guarantee that the members will use the accommodations which we must purchase for them.

§ Anyone may make arrangements to arrive at Columbia University as early as June 15, 1964, and/or remain as late as July 3, 1964. For the cost of such additional accommodations beyond our basic six-day "Package," please consult our Arrangements Chairman, Walter Wynne.

‖ Upon request, deposits will be refunded up to May 15, 1964.

THE 1964 NEW YORK WORLD'S FAIR

The World's Fair will bring thousands of people to New York while we are holding our Third I.F.S.C.C. Congress. Many groups are already making reservations that conflict with our arrangements. Therefore, only by making deposits by June, *1963*, on room reservations for June, *1964*, will Columbia University guarantee us accommodations for more than 280 people. We expect at least 500 to register for the 1964 I.F.S.C.C. Congress and rooms will be assigned upon receipt of $25 *per person* in the following order of priority:

1. Members of societies affiliated with the I.F.S.C.C., other than U.S.A. members
2. U.S.A. members
3. Non-members

After June, *1963*, there will be no order of priority!

PROPOSAL FOR SCIENTIFIC PROGRAM

Members and their Colleagues are urged to submit one or more proposals for consideration by the Committee on Scientific Programs. Suggestions as to names of speakers to be invited would be greatly appreciated. Titles and abstracts (Original and 5 Copies, Typed in Double Space), on this sheet or facsimile, should be in the hands of the Chairman, Dr. Emil G. Klarmann, 5 Roosevelt Place, Montclair, N. J., as soon as possible but not later than *Dec. 15, 1963.*

Exact Name(s) of Presenter(s):
Institution or Address: (Complete for Each Author)
Title of Presentation: (Indicate Clinical Applications, if any, in Title)
Abstract: (*This should be specific as possible*)

Conditions:

1. It is understood that this material has not been published elsewhere.
2. No author may read more than one paper.
3. Papers will be limited to 20 minutes, and this time limit will be strictly enforced.
4. All papers read at the meeting shall become the property of the Society.
5. A copy of each paper to be read at the meeting shall be deposited with the Chairman before *March 15, 1964.*

- -

RESERVATION FORM

Name (Please Print)________________	Arrival Date________________
________________	Departure Date________________
Address________________	Number in My Party:
________________	Adults________Children________
________________	Deposit(s) at $25 each________
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Note: Make checks payable to Society of Cosmetic Chemists

Mail This Reservation Form To: Walter Wynne, Arrangements Chairman
321 West 44th St., Room 700
New York 36, N. Y.

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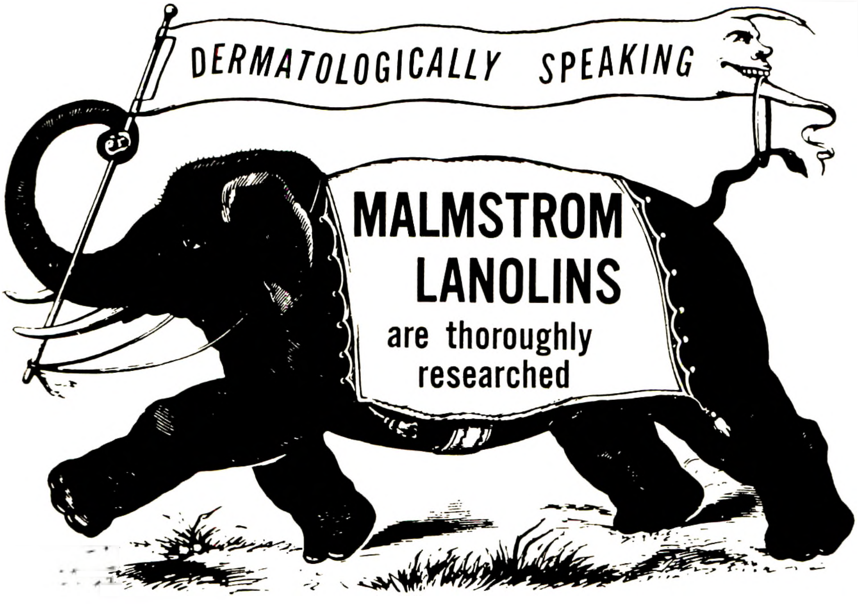
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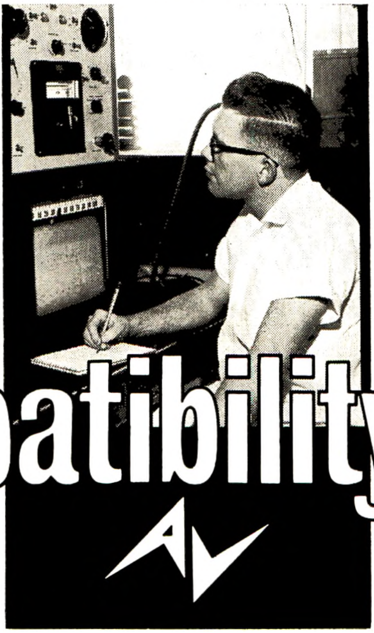

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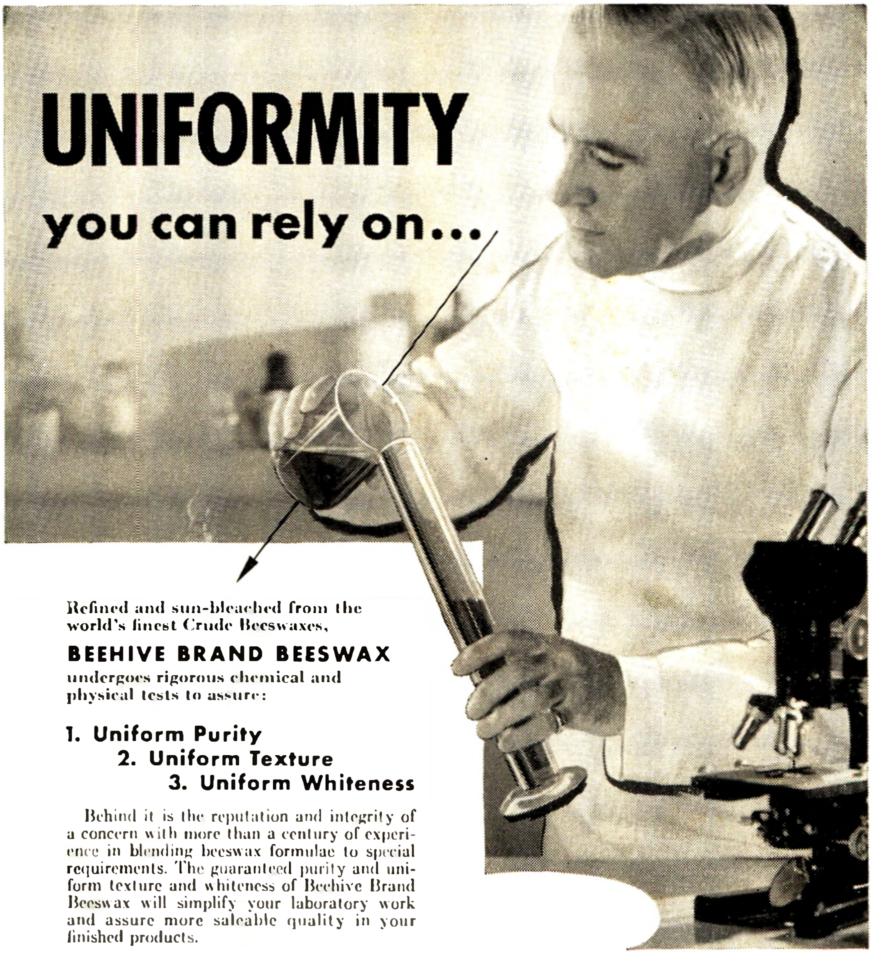

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