Jaocs News Feature

Shortages and regulations: headaches for toilet soap formulators[1]

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The formulator is faced with shortages in soap stock fats and oils and must juggle the merits and costs of less common oils, lower grade greases, and synthetics as substitutes for familiar beef tallow and coconut oil. Best compromises must be made by the perfumer for essential oils no longer obtainable to maintain quality and to preserve the odor image of soap products. The formulator must have in vitro, in vivo, and safety data for soap additives. All through development, the formulator must remember that, having made it, he must prove it. Efficacy tests must be more detailed and closer and closer to life.

INTRODUCTION

The soap formulator is in the midst of conflicts over shortages and regulations. Shortages make him devote an increasing share of his time to finding substitutes for old, familiar standbys. This cuts down on new product effort and so gives him a marketing headache. Regulations demand and receive an increasing amount of money for safety and efficacy testing. This gives him a budget headache. There is no easy relief in sight for the formulator; he must learn to cope. Of the many shortages, coconut oil and perfume essential oils are uppermost. Of regulations, those of the Food and Drug administration (FDA) dealing with new drugs in over-the-counter (OTC) products and those of the Federal Trade Commission (FTC) with documentation of advertising make big inroads on the research and development budget.

[1]Presented at the AOCS Meeting, Mexico City, April 1974.

SHORTAGES—SOAP STOCKS

Shortages of soap stocks are nothing new. Early settlers made soap once a year in the fall at hog killing time and thought themselves lucky to have abundant wood ashes for homemade lye. Perfume was supplied by stirring the batch with a sassafras stick. Most people made do with grease soap for all purposes. They were accustomed to hardship and privation, and, if the soap stung their eyes or burned when it touched a cut, they paid scant attention.

Good quality soap, although not cheap, was available in the 1800s. Most authors, from 1850 on, agreed that 10-25% coconut oil, with the remainder tallow, was ideal. Olive oil, palm oil, and cottonseed oil also were used; and, during shortages in World War II, soybean, corn, peanut, and tall oils were suggested. Potash soap was recommended. The synthetic production of lauric acid was seen as a possibility. Mostly, people did without; and, in a typical toilet soap, the coconut oil content dropped from 25 to 7%. White grease or lard was added when the coconut oil hit the low point.

Today, shortages have struck again. Coconut oil is $.50/lb; tallow, $.18/lb; and other possible alternate oils have moved into the $.25-$.35 range. In a $10.00 case of soap, the soap stocks formerly ca. $1.20 now cost $3.20. What can the formulator do to cut costs? As always, the first suggestion is to cut the coconut oil.

The findings of past authorities have been reexamined at Colgate-Palmolive over the years. In 1969, a series of soaps was made up from stocks of a range of coco/tallow ratios (R.E. Compa, Colgate-Palmolive, unpublished results). To the basic coco/tallow stocks of one set was added 10% of the unsaturated oils: olive, linseed, castor, sesame, and soybean. Companion soaps were made of the same coco/tallow ratio, the one from tallow of 42 C titre, the other from tallow of 45 C. Bars were laboratory tested for rate of solubility. Table I gives the results.

Solubility rate of the all coco soap was ca. five times that of the all tallow

TABLE I

Effect of Coco/Tallow Ratio upon Solubility Rate of Soap

Coco	/ Tallow	Unsaturated oil[b]	Solubility (95 F) g/min
100	0		0.125
0	100 (42)[a]		0.025
10	90 (42)[a]		0.028
15	85		0.052
20	80		0.063
15	75 (42)[a]	10	0.065[c]
20	70	10	0.070[c]
20	80 (45)[a]		0.035

[a]Titre of tallow portion. Number in parenthesis indicates temperature in C.

[b]Boils were made with olive, linseed, castor, sesame, and soybean oils.

[c]Solubility data averaged on soaps containing unsaturated oils.

TABLE II

Effect of Adding Potash Soap[a]

Soap base (%)	Abrasion lather test[b] strokes water temperature (F) 55	85
10% Potash 90% Soda	63	47
100% Soda	81	48

[a]Base soap: 15 coco/85 tallow.

[b]Tests made in water of 125 ppm calcium carbonate hardness.

TABLE III

Field Testing Soaps of Three Coco/Tallow Ratios

Soaps compared	Preference ratio
15/85 vs 20/80	4:3 for 20/80[a]
15/85 vs 25/75	2:1 for 25/75[a]

[a]In both panels, ca. 30% detected no difference in lather.

soap. Solubility rate changed little with the addition of 10% coconut oil to the tallow but took a sharp jump at the 15% level. Addition of 10% of the unsaturated oils increased the rate of solubility. Substitution of very high titre tallow cut the rate of solubility in half. A project in 1964 (G.N. Apostolatos, Colgate-Palmolive, unpublished data) compared bars of all soda soap with bars containing 10% potash and 90% soda soaps. Table II shows that the addition of 10% potash soap sped lather formation in cold water but made no improvement in warm water.

A large scale field test of 1964 (D. Riley, Colgate-Palmolive, unpublished data) compared soaps of three coco/tallow ratios. Table III shows that ca. 30% of the users could detect no difference between soaps of different blends, but, among those who could discriminate, the preference went for the bar with the higher level of coconut oil soap–by a small margin when 15/85 was compared to 20/80 but by a larger margin when 15/85 was compared to 25/75.

In a plant run of 1969 (J.H. Pickin, unpublished data), grease and tallow were blended to titre requirements indicated by laboratory work, and, from these stocks, 15/85 and 20/80 coco/tallow blends were prepared so that the resultant soaps were of identical rates of solubility. These bars were field tested, and, again, the panels could detect the lather difference and voted for the bar of higher coco soap content.

What users observed was not just rate of solubility or lather quickness but bubble size. Photographs taken as panelists lathered their hands showed that the difference in bubble size between the lather of bars of 20/80 and 25/75 soap blends was small; but, between bars of 15/85 and 20/80 and 15/85 and 25/75, the difference was much more marked. Usually, the larger bubbles were associated with the bar of higher coco soap content (G.N. Apostolatos, Colgate-Palmolive, unpublished data).

All the evidence indicates that coconut oil is still essential to good quality toilet soap and that users, particularly when their attention is called to it, will note favorably the bar of higher level.

Synthesis of the typical coco fatty acids was suggested in 1942, and, in the past 10 years, both straight chain and branched chain types have appeared. So far, production has been in pilot plant rather than commercial quantities. Table IV shows that both types are higher in C_{12} or C_{12} centered fractions. They can be substituted at 75% of normal usage of coconut oil to yield soaps of equivalent lather.

Synthetic detergents have been substituted for soaps, and problems have been noted in processing of the bars and in consumer acceptance. Many of the patents on all synthetic or syndet/soap combinations comment on the necessity to achieve a soap-like feel to gain user approval. Today, such bars are only 20% of the market. The umbilical cord to naturals has not been cut for this 20%, for the three most successful in this category are still dependent upon coconut oil, either as a starting material for the detergent portion or as an ingredient of the soaps used. The $.12-$.13/lb cost of the petrochemicals make them attractive, but the formulation problems, poor consumer acceptance, and current cutbacks in aliphatics and aromatics may act to deter any shift away from traditional soap.

Low grade tallows and greases are suggested but may cost more in treatment than the premium for quality stock. The extra fancy tallow, bleachable fancy tallow, and white grease are regularly available and differ from each other in declining cost by from $.0025-$.0075/lb. Tallows of extra fancy grade will require only 1% of bleach material, of the bleachable grade from 1-2%, and greases may need over 3% of total bleach. It can be seen from Table V that, if a low grade fat requires $.12 for bleach treatment, it would be more economical to spend $.005/lb for extra quality tallow that could be bleached for $.04.

The soap maker of today, as of 30 or 70 years ago, is still dependent upon high quality coconut oil and tallow for toilet soap. Until the consumer is willing or forced to put up with a bar of drastically different performance, there does not seem to be much possibility of a change.

SHORTAGES–PERFUME OILS

The soap formulator must, above all else, see to it that his toilet bar has a pleasant smell. He knows, from both solicited and unsolicited consumer response, that the product is put to the nose first and the lathering comes second. If the smell is not agreeable or is wholly out of place with the image built up by advertising, then usually the user finds fault with all other attributes of the soap, no matter how much money has been lavished on lather, deodorant, or moisturizing properties.

Ca. 70 years ago, perfumes for soaps were compounded from natural oils, and perfume formulas were relatively simple. Ca. 50 years ago, some synthetics, like hydroxycitronellal, benzyl acetate, methyl anthranilate, and diphenyl oxide had appeared, but bergamot, bois de rose, geranium, lavender flower, patchouli, sandalwood, and vetivert were recommended in significant percentages (1). In the past, natural oils disappeared from the market when war or disaster cut off the source; but today high labor costs, no labor at all, and high shipping costs have the same effect.

TABLE IV

Fatty Acid Distribution

Fatty acid	Natural coconut oil (%)	Synthetic coco types Straight chain (%)	Synthetic coco types Branched chain (%)
C_8	8		
C_{10}	7	9	
C_{11}			18
C_{12}	48	66	42
C_{13}			40
C_{14}	18	25	
C_{16}	9		
C_{18}	10		

TABLE V

Fat Treatment Cost vs Quality Premium

Bleach material (%)	Cost[a] case (cents)	Extra cost for fat quality (cents/lb)	Cost case (cents)
1	4	1/4	2.7
2	8	3/8	4.0
3	12	1/2	5.4
4	16	3/4	8.0

[a]Includes bleach materials and losses incurred.

TABLE VI

Common Essential Oils: Frequency of Use in Perfume Formulas

Essential oils	Perfumes for soap % formulas	Flowery scents % formulas
Synthetics		
Anisic aldehyde	17	20
Benzyl acetate	42	16
Coumarin	29	8
Heliotropin	12	18
Linalyl acetate	4	5
Linalool	1	26
Phenyl ethyl alcohol	28	54
Terpineol	50	44
Naturals		
Cedarwood	22	--
Lavandin	11	--
Lavender spike	12	--

TABLE VII

Toilet Soap Perfume

	Year		
	1900	1950	1973
Components	12	35	154
Cost compared to current base	10 X Base	2 X Base	Base

Synthetics were at first thought suitable only for low cost soaps and as cheap substitutes to give some variation to the ever present citronella, at one time the most common perfume for household soap (2). Mentioned as useful were benzyl acetate, diphenyl oxide, phenyl ethyl alcohol, and terpineol. In the 1930s, cedarwood oil, a cheap natural, was useful as a fixative of low cost perfumes.

Today, the synthetics have become increasingly important as building blocks, along with the more available naturals, of whole series of perfumes. Table VI shows how commonly certain widely used synthetics and naturals appear in formulas specifically for soap (3) and formulas for flowery scents in general (4).

Recent lists of shortages have included all of these prime synthetics (5), and, to the list of naturals, have been added eucalyptus, petitgrain, pine needle, rosemary, and ylang ylang. Reasons for shortages range from lack of acetone necessary to the production of linalool and linalyl acetate, to lack of labor in the harvesting of eucalyptus. The synthetics now have become vitally necessary, because they maintain the characters of perfumes that once depended upon naturals.

How the expensive naturals are replaced by cheaper components can be illustrated by bergamot for which lemon oil, suitably supported, may be substituted. Terpinyl acetate which has been used to adulterate bergamot (6) also must be considered a substitute. The price range is: bergamot, $17; lemon oil, $7; and terpinyl acetate, $1.

Whether or not the perfume characters have been maintained throughout the progression of changes is for the expert or the loyal user with the better than average nose to determine and regret.

The perfume for a famous national brand of toilet soap, sold for over 100 years, has undergone many reformulations over the years to enable the brand to stay competitive in cost. Were the perfume compounded today of the oils specified in the original formula, added to the soap at the original concentration, the cost of the perfume alone for one case would be equal to the cost of 10 full cases today. The perfume has become much more complex, compared to the original, as synthetics have replaced the natural oils. Table VII indicates the changes in number of ingredients and relative costs.

Perfumers of a generation or two ago found their formulation horizons extended by the introduction of synthetics, many of which now have become important building blocks for all perfumes. Today, the supply of these basics has been threatened by sudden shortages of synthetic starting materials. Cheap naturals have disappeared because of lack of labor. However, perfumes have persisted over many years, still retaining something of their old characteristics despite many vicissitudes. There is every reason to hope that still newer synthetics and formulation ingenuity will perpetuate old favorites.

REGULATIONS—FDA

The soap formulator, if not an expert himself, must be knowledgeable enough to ask advice about the regulations of the FDA, whose principal concerns are the safety, efficacy, and label claims of foods, drugs, and cosmetics, and the FTC, one of whose duties is the control of deceptive advertising.

The formulator probably knows that soap was specifically excluded from the regulations of the Food, Drug and Cosmetic Act of 1938 and of all amendments since (7). However, if active ingredients, such as bacteriostats, are added to the toilet soap formula for the purpose of making antibacterial claims on the label, then the product becomes a drug and is subject to all the provisions of the Act and its amendments.

The Act of 1938, and particularly its amendment of 1962, emphasizes the difference between established drugs generally recognized as safe (GRAS) and generally recognized as effective (GRAE) under label conditions and new drugs, by definition, "not generally recognized as safe and effective." The procedures by which a new drug may be cleared for use are set out in the 1962 amendment.

In the past 10 years, all the bacteriostats commonly used in soaps, with the exception of hexachlorophene (until 1972), have been classed as new drugs.

To assure himself that he has a reasonably effective product, the formulator already has done the usual in vitro tests, like test tube serial dilution, to determine efficacy at low dilution and gelatin disc halos of inhibition to judge degree of substantivity. To assure himself that it is reasonably safe, he has sent the product out for the series of animal tests prescribed by the Federal Hazardous Substances Labeling Act. These include acute oral toxicity in rats, acute dermal toxicity in rabbits, primary skin irritancy in rabbits, and eye irritancy in rabbits.

However, if the product contains a new drug ingredient, then a New Drug Application (NDA) (8) must be filed with and approved by the FDA before the product can be manufactured and sold. The NDA is primarily a documentation of how effective and how safe the new drug is but also contains details on label copy, manufacturing, packaging, quality control, and long term stability. Safety tests with animals, and both safety and efficacy tests with humans, are required for an NDA.

However, before any human tests can start, the formulator must file an Investigational Exemption for a New Drug (IND) (9).

The IND identifies the new drug or product and the new drug ingredient which is the specific component that, by definition, is "not generally recognized as safe and effective." Included in the IND are: descriptions of the new drug ingredient; and the way it is to be administered; formula of the new drug; specifications for all components; statement of methods and controls for manufacturing and packaging the new drug; all preclinical information, such as animal studies; identification of investigators who originally concluded that the new drug was reasonably safe for use in humans; and, most importantly, an outline of the human clinical tests planned, with full details on how case histories of the individual subjects are to be kept and effects evaluated.

Of prime importance for the IND are the basic animal safety studies, as outlined in the 1961 Regulations of the Federal Hazardous Substances Labeling Act (10). The oral toxicity studies probably will be expanded to include several species, not just rats. In addition, there will be data on blood levels of the new drug ingredient after oral or dermal exposure, correlated with what organs the new drug ingredient eventually has lodged in, and how the organs have been adversely affected. Also required will be the determination of the no effect level of the new drug ingredient. New techniques have had to be developed for measuring ppb in the blood.

Given great importance after the thalidomide episode are reproduction studies. Guidelines were written in 1966 (11) which indicated studies of: (A) fertility and general reproductive performance, (B) teratogenic effects (malformation), and (C) perinatal and postnatal effects (just before and just after birth). More recent has been the

requirement for mutagenic studies (permanent effects on the inherited characteristics). The tests involve mice, rats, rabbits, and dogs.

Human tests, conducted under the IND, can include the observations by a qualified physician of the effects of normal daily usage of the toilet soap by a panel of hundreds or thousands, studies on degerming the hands by the Cade test or glove juice test, and studies of how regular use of the soap affects such skin ailments as diaper rash or minor infections. All of this data the formulator will include in the NDA.

Having an NDA approved is no assurance that, at some time in the future, it may not be rescinded. Toxic effects unsuspected and occurring only with a frequency of one in a million subjects, misuse of the product, or manufacturing blunders may crop up and cause the product to be withdrawn.

A case in point is that of hexachlorophene, long a GRAS drug recognized as safe and effective and established in the U.S. Pharmacopeia. Hexachlorophene could be formulated in toilet soaps at economical, effective levels, with only concerns being assaying of the product and proper labeling. However, in a series of rulings beginning in January and ending in November 1972, hexachlorophene was first limited to 0.75% and then effectively banned from OTC products.

Since dealing with hexachlorophene, the FDA has left the fate of other soap bacteriostats up to the OTC Antimicrobial Panel I, which has proposed that active antimicrobial ingredients be classified in the following categories: (A) GRAS and GRAE, (B) not GRAS and GRAE, and (C) more study needed.

The panel has developed tentative definitions for a series of products and will produce a monograph proposal like that already issued on antacids.

Comments of the FDA commissioner on the antacid monograph proposal indicated (12) some general principles that may apply to other OTC drug monographs. These were: (A) if a drug ingredient falls in category B, the manufacturer will have a 6 month period to reformulate, remove, or file an NDA on his product; and (B) if a drug ingredient falls in category C, a 2 year period after publication of the final monograph is reasonable for completion of all required additional testing for the category C ingredients.

In a period of rapid change, the soap formulator must guard against being overtaken suddenly by events. He must keep abreast of clinical findings in the cosmetic, medical, and dermatological journals as they apply to the drug ingredient of his NDA. In particular, he should become a close, critical reader of digests like the *F-D-C Reports*, of the ponderous *Federal Register*, and, lately, of the minutes of the OTC review panels. He should not overlook reading the daily newspapers, because a news leak, true or false, may make reformulation necessary long before regulations are issued.

REGULATIONS—FTC

The soap formulator, having made the product, must prove that it performs, and, today, the proof of advertising claims (not label) must convince the FTC. The FTC regulates deceptive advertising by virtue of powers granted by the FTC Act. The act defines false advertisement (of food, drugs, devices, or cosmetics) to mean:

> an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combinations thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual.

Acting under this directive, the FTC in 1972 demanded advertising substantiation from 28 manufacturers of 70 soap, detergent, moisturizing, and cleansing products making special cosmetic, deodorant, and drug claims. Details of testing procedures and competitive results were placed on public reading August 1973. The claims and substantiation for 7 toilet soaps with combined sales of over 50% of the national market were revealed in summary in *F-D-C Reports* (13). Deodorancy claims were substantiated with data on axillary odor reduction in panels of 10-80 men and women. Claims for effectiveness in relieving dermatitis and in preventing minor skin infections were upheld with the results of human panel tests. For a bar claiming nondrying of the skin, panel test results vs both soap and cold cream were provided.

Major efforts are made by industry, in response to requests by both FDA and FTC, to bring test evaluation of products as close as possible to actual usage. A good example of this is the recent replacement of the 35 year old Price handwashing test by the glove juice test to bring hand degerming studies as realistically close as possible to the real life situations of surgeons in operating rooms.

In addition to reports on what was handed over to the FTC, medical and cosmetic journals of the past 10 years have published papers in which manufacturers of leading toilet soaps have given details of testing. Indications are that, to support a major brand, dozens or scores of supervised human clinical tests have been conducted. Since the cost of a single panel subject may range from $100.00-$500.00, depending upon the test, it is apparent that the full documentation of a deodorant, antibacterial toilet bar may range from 500 thousand-over a million dollars.

However, long before he has submitted data to the FTC, the soap formulator has paraded his documentation in many sessions with the legal staff of his own company, the legal staff of the advertising agency handling the brand account, and, a final hurdle, the legal staff of the major network that will air his commercial on TV.

Locally distributed products of small sales still may get away with far out claims which have no obvious means of support, and the sales staffs are sure to hound the soap formulator with endless requests that the claims be emulated. However, for nationally distributed and advertised brands in the full glare of publicity, the soap formulator must ensure that even his modest claims are supported extensively and convincingly.

In dealing with fat stock shortages, the formulator still can get guidance, if not comfort, from the experience of the past, since the consuming public is conservative about soap, likes its feel and smell, and does not want change.

The shortages of essential oils, particularly the important synthetics, pose problems for the perfumers bigger than any problems of the past. In the future, perfume formulas will become even more complex.

Regulations will not go away; they are here to stay. The formulator must become vitally aware of regulations, alert to all sources of information about them, and learn to live with and not fight them. All of this must be accomplished with as little strain on the budget as possible.

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Program announced for Glycolipids Short Course

Lloyd A. Witting, Denton, Tex., general chairman of the AOCS Short Course on Glycolipids, has announced that 21 presentations are scheduled for the three day meeting to be held June 5-8, 1975, at the Given Institute, Aspen, Colo.

The tentative schedule is as follows: "Nomenclature of Glycosphingolipids," Robert M. Burton, Washington University School of Medicine; "Extraction and Analysis of Materials Containing Sialic Acid," Eric G. Brunngraber, Illinois Department of Mental Health; "Nervous System Gangliosides," Robert Ledeen, Albert Einstein College of Medicine; "Gangliosides of Nonnervous Tissue," John R. Wherrett, University of Toronto.

"Studies on the Distribution of Gangliosides in Tissues by Immunological Techniques," Donald M. Marcus, Albert Einstein College of Medicine; "Glycolipid Turnover in Tissue Culture," Michel Philippart, University of California, Los Angeles; "Synthetic Inhibitors of Glycosphingolipid Metabolism," Norman S. Radin, University of Michigan; "Enzyme Replacement Therapy for Gaucher's Disease: A New Dimension in Sphingolipidoes Research," Peter G. Pentchev and Roscoe O. Brady, National Institutes of Health.

The following presentations also are planned: "The Metabolism and Function of Phosphoglycosyl Diglycerides," Ronald Pieringer, Temple University School of Medicine; "Sulfatides: Major Glycolipids of Chordate Testis and Spermatozoa," R.K. Murray, University of Toronto; "Structure of Extracellular Glycolipids Produced by Yeast," Alexander P. Tulloch, Prairie Regional Research Laboratory; "Biosynthesis of Steryl Glucosides and Acylated Steryl Glucosides in Plants," Alan D. Elbein, University of Texas Health Science Center; "The Role of Mono and Oligosaccharide-Dolichol Derivatives in the Biosynthesis of Mammalian Glycoproteins," Edward Heath, University of Pittsburgh School of Medicine; "Metabolism of Sugar Polyprenols in Plants," W.T. Forsee, University of Texas Health Science Center.

In addition, the following are scheduled: "Structure Studies on Human and Canine Intestinal Fucolipids," John M. McKibbin, University of Alabama; "Gastric A- and B-Active Glycolipids: Micro- and Macroheterogeneity," Martin I. Horowitz, New York Medical College; "Specific Microanalysis of Intact Fucolipids and Other Glycolipids by Mass Spectrometry," Karl A. Karlsson, University of Goteborg; "Blood Group Glycolipids in Normal and Tumor Tissue," Sen-Itiroh Hakomori, University of Washington; "Fucolipids and Viral Transformation," Sheldon Steiner, Baylor College of Medicine; "Biosynthesis in Vitro of Neutral Glycosphingolipids in Normal Tissues and Cultured Cells," Subhash Basu, University of Notre Dame; "Studies on the Use of Carbohydrate Containing Ligands in the Affinity Chromatography of Neutral Glycosphingolipid Hydrolases," Charles C. Sweeley, Michigan State University.

John R. Wherrett, Alan D. Elbein, and John M. McKibbin will serve as chairmen for various sessions.

Final plans for housing, social events, fees, and travel arrangements will be announced at a later date. Further information will be available, after Jan. 1, 1975, from: Executive Director, AOCS, 508 S. Sixth St., Champaign, Ill. 61820. ■