It is apparent that each resin must be evaluated individually in the elastomer combination to be used by the customer. Few general predictions can be made concerning the tackifying properties of other types of any resin in any elastomer, and even excellent tackifying effectiveness in one elastomer does not guarantee the same excellent properites of other types of synthetic rubber. For instance, although the NIREZ polyterpenes have been found to be superior adhesive resins when used with natural and most synthetic rubbers, the use of this series of resins with Neoprene is not recommended.

Newport has increased its research efforts in the field of adhesives in the firm belief that the usage of rosin and turpentine based resins will continue to grow. Many petroleum resins are being advanced as potential adhesive additives. An expanded program of research and technical service will be needed to maintain the superiority of naval stores products. Such a program is considered essential if the naval stores industry is to achieve its full potential in the expanding usage of rubber-based adhesives in the packaging and consumer market of tomorrow.

INVESTIGATIONS ESTABLISHING THE SAFETY OF ROSIN PRODUCTS FOR FOOD PACKAGING APPLICATIONS

by

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Webster defines rosin as a resin obtained from turpentine by distillation, whose uses are numerous and well-known. Frankly, this is a poor definition, but I must agree that its uses are numerous and certainly well-known to this audience.

Noteworthy in its absence from this definition is any comment to the effect that rosin is safe. I think all of us knew this years ago, but in 1958 Congress declared rosin as a "poisonous and deleterious substance." This is not stated with cynicism, but with an understanding of a basic change in thinking by society--as reflected by Congress--on matters of public health. Prior to the last 10 years the average American was satisfied that adequate protection of the public was provided by laws that authorized the Government to prevent further sale of a product which could be proven to be unsafe--policing laws. However, with the advent of chronic toxicity, the agument was advanced that by the time the Government could prove such a case, irresponsible action on the part of a manufacturer could do irreparable damage to the public. As a consequence, in the field of public health we have started a shift to licensing laws--those which assume everything to be unsafe until proven otherwise to the satisfaction of the government.

I say we have started on this shift to licensing laws, because we have, in fact, only started. Drugs, pesticides, and food additives including packaging chemicals have come under this form of legislation. It is safe to predict that cosmetics will soon be covered by similar legislation, as well as all other environmental chemicals, including water and air pollutants, household substances, and natural food stuffs. The aim is to eliminate everything from our environment which might contribute to chronic, debilitating disease.

It is in this frame of reference that rosin was suspect, not because of any positive data on hazard, but the absence of data on safety from prolonged exposure.

Shortly after the Food Additives Amendment was passed, Hercules and several other rosin producers requested an opinion of the Food and Drug Administration on the safety of rosin and rosin-based products. We were informed that they could not consider them safe for the many extensive and diversified uses they enjoy without the conventional long term, 2-year chronic feeding studies in rats and dogs, and evidence based on these studies that they were safe to animals at 100 times the level in the diet of man.

I am certain I need not point out that this opinion presented Hercules with a major policy decision. Because of the vast number of products involved and their variety of uses, could we do the job on our products or would our customers have to do it? Our first step was to contact as many of our customers as possible and determine which products were most important to them and how they were used. Without this cooperation of our customers we could not have made an intelligent decision on the importance of the products nor could we have designed proper experiments to cover their uses.

Of our more than 70 rosin products, we concluded that 34 of these were used in sufficient volume by our chewing gum, flavor extract, paper, adhesive, cellophane, and coating customers to justify the expense involved in conducting these studies. The remainder did not. We also concluded that with only rare exception our customers could not justify the expense on the basis of his individual use of these products. Consequently, the inevitable decision was made that Hercules would undertake the project.

Our next step, quite understandably, was an evaluation of the need for extensive toxicological studies on all 34 of these products. Simple arithmetic of a minimum price of $50,000 per compound times 34 told us we faced an expenditure of 1-3/4 million dollars just for animal studies. Based on various analytical data on composition, we were able to design a more limited program that we believed would properly evaluate safety and yet avoid unnecessary duplication. This program was presented to the Food and Drug Administration and accepted in advance. It is this program that was announced several years ago, and which I will describe.

Let me start by explaining our thesis. We proposed to the Food and Drug that 2-year chronic studies in two species would be necessary only for those rosin products which had basically different resin acid components, and that 90-day subacute studies in one species would be adequate for the simpler derivatives (salts, esters, and addition products) provided these confirmed no greater toxicity than the parent rosin. The Food and Drug Administration agreed, except that products of different neutral components would also require 2-year studies.

The types of rosin products which were selected for both types of investigation are shown on the first two figures along with some of the types of products which were not investigated. The first of these tables shows the basic rosins and modified rosins.

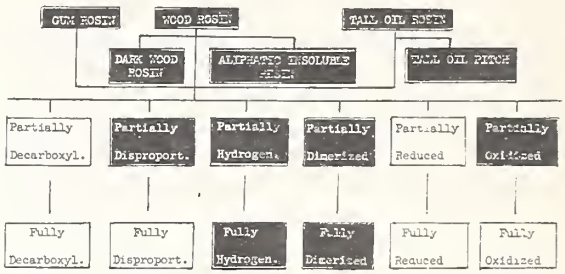

Figure 1.--Basic rosins and modified rosins.

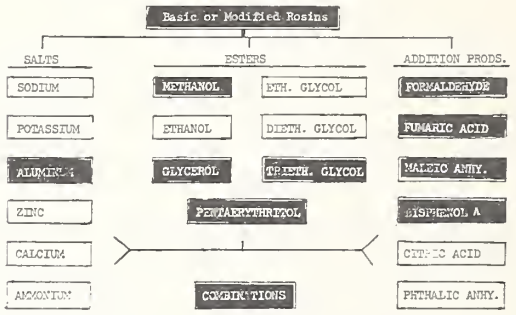

Figure 2.--Rosin derivatives.

The darkened blocks indicate those which were selected for study; no studies were conconducted on the others.

Gum Rosin was selected for its traditional importance to the paper industry and received the full 2-year study.

Wood Rosin, although it contained approximately the same resin acid composition as gum rosin, was fed for 2 years because the neutral fractions was different.

Tall Oil Rosin was also fed for 2 years because it contains a different neutral fraction than the other two sources.

Dark Wood Rosin and the aliphatic insoluble resin (Vinsol) were fed for 2 years because they contain different resins and resin acids which are partially oxidized.

Partially Disproportionated Rosin (Resin 731D) was fed for 2 years because it contains

far more dehydroabietic acid than the other resins and a different neutral fraction.

Partially Hydrogenated Rosin (Staybelite) was fed for 2 years because it contained a very high level of dihydroabietic acid and a different neutral fraction.

Fully Hydrogenated Rosin (Foral) received similar long-term examinations because of its high content of tetrahydroabietic acid and also a different neutral fraction, due to different catalysts and reaction conditions.

Fully Dimerized Rosin (Dymerex) was fed for 2 years because of its very high dimer content and different neutrals.

Partially Dimerized Rosin (Poly-pale), although containing less dimer than the fully dimerized product, contains somewhat different neutrals and required the full 2 year examination.

Partially Oxidized Rosin is not a specific commercial product of Hercules, but is included in the figure to indicate that the partial oxidation was investigated indirectly by the feeding of dark wood rosin, whereas extensive oxidation has not been studied.

Figure 2 shows the major types of rosin salts, esters, and addition products. The shaded ones only were selected for animal feeding studies. As can be seen, different types of reaction products were studied. However, because many combinations of these reaction products are commercially important, a total of 24 products were fed for 90 days. For example, the glycerol ester of wood rosin, partially hydrogenated, partially dimerized, and fully dimerized were all fed. Likewise, the pentaerythritol ester of wood rosin and the pentaerythritol ester of maleic modified wood rosin were both fed.

In addition to the 24 subacute studies, we were required by the Food and Drug Administration to feed one of these derivatives for 2 years to both species to provide assurance that the mild reaction conditions did not alter the long-term toxicity of the neutrals. For this, we selected the Pentaerythritol ester of wood rosin (Pentalyn A). While we are on the subject of the feeding studies, let me briefly describe the design of these experiments and the results, before I describe the migration studies on these products.

Table 1 shows the basic design of our 90-day subacute studies. As can be seen,

Table 1. --Design of subacute studies

Dietary levels (pct.)	No. of rats (per product)
5.0	20
1.0	20
.2	20
.05	20
.01	20
Controls	20 x 14
Total 3,080	

five dietary levels were selected for each of the basic rosins and each of the rosin derivatives. Because it was impossible to initiate all of these studies on the same day, 14 control groups were employed. As you can see, each of the 34 products was fed to 100 rats equally divided, 10 of each sex, between 5 dietary levels ranging from 0.01 percent and 5 percent.

Table 2 shows the basic design of the 2-year chronic studies. All of the basic

Table 2. --Design of chronic studies

Dietary levels (pct.)	No. of rats per product	No. of dogs per product
1.0	60	6
.2	60	-
.05	60	6
Controls	60 x 4	6 x 2
Total 1,680		138

rosins were fed at two dietary levels--1.0 and 0.05 percent. Three were fed also at the dietary level of 0.2 percent. The rosin ester, Pentalyn A, was fed only at the level of 0.05 percent. Four control groups of rats and two control groups of dogs were employed. Each group consisted of 30 male and 30 female rats, and 3 male and 3 female dogs. All of these experimental animal studies were conducted and designed by Hercules,

with advice from the Food and Drug Administration, but were conducted under contract by the Industrial Bio-Test Laboratories, of Northbrook, Ill.

Table 3 is an attempt to itemize the most significant toxic effects which were noted in

Table 3. --General toxicological effects

Item	Feeding level (pct.)	Basic and Modified rosins	Derivatives of rosin
Mortality	5	Most	Few
	1	None	None
Growth	5	All	Few
	1	Most	Few
	0.2	None	None
Organ wts.	5	All	All
	1	Most	Most
	0.2	None	None
Histopath.	5	Few	Few
	1	None	None

examination of almost 5,000 rats and 138 dogs. Not listed are the thousands of examinations which were made and which revealed normal results, including, for example, hematology, blood chemistry, liver and kidney function tests, urine chemistry, tumor incidence, and histologic examination of more than 20 organs and tissues. Very briefly, with most of the basic rosins, but with only a few derivatives, the animals died on the 5-percent dietary levels. No mortality occurred with any of the rosin products at the 1-percent dietary level. Growth was impaired at the 5 percent level with all of the basic rosins and a few of the derivatives. At the 1-percent level most of the rosins impaired growth but only a few of the derivatives. At 0.2 percent no growth effects were observed with any of the products. The difference in growth and mortality between the basic rosins and the derivatives was concluded to be due to the greater free acidity of the basic rosins, which caused intestinal irritation and food refusal.

Effects on organ weights were generally restricted to the liver, except for an effect on the kidneys and testes by a few types of rosins. All of the products produced marked liver enlargement at the 5-percent level, and most of the products caused some degree of enlargement at the 1-percent level in both species. No organ weight effects were observed at the 0.2 percent level. Histopathologic changes were present mostly in the liver, with the few exceptions noted above, and were restricted to the 5-percent dietary level.

The feeding tests have demonstrated that the "no effect" or safe dietary level of the products selected for these toxicological tests is 2,000 p.p.m. for some and 10,000 p.p.m. for others.

Now, let us shift our discussion to the other phase of our investigation that was designed to evaluate the quantity of rosin products contributed to the human diet from all the various uses which rosins enjoy. As many of you realize, we have subscribed to a philosophy in this country, which has recently been endorsed by the World Health Organization and Food and Agricultural Organization of the United Nations, that we should not permit food additives in man's diet unless it is safe to experimental animals at 100 times the level contemplated in the human diet. The original basis for this conservativeness is cited as a device to compensate for our lack of precise means of predicting the effect of a compound on the most sensitive human. I like to call it an "ignorance factor," but more traditionally it is called a "margin of safety." The figure is based on the assumption that man is 10 times as sensitive as the experimental animals and the most sensitive human is 10 times as sensitive as the average. Experience has taught us that this factor is overly conservative.

To determine whether a 100-fold margin of safety existed for the rosin products, information was required on the amount contributed to food from the use of these products as sizing agents, tackifiers in adhesives, plasticizers in wax coatings, modifiers in coatings, and masticatory substances in chewing gum--the major uses in which human food are associated.

Usual methods of chemical analysis were not satisfactory or adequate for most of these studies for obvious reasons; therefore, we resorted to the use of radioactive techniques. Time did not permit us to grow pine trees in a radioactive carbon dioxide atmosphere and collect the radioactive rosin. However, after many preliminary experiments, we developed a procedure to introduce tritium,

radioactive hydrogen, into the rosin molecule by the Wilzbach random-tagging procedure and thus were able to prepare many of these products to contain a uniform "tag" on all components including the neutral fractions. For other rosin products, as rosin esters, we were able to esterify the rosin with C^{14} tagged alcohol.

Rather than devote the entire time allowed to a discussion of the details of how these experiments were conducted, I believe it would be more appropriate to show you the results of a few of our migration experiments. In all of these experiments, we were again indebted to many of our customers who supplied us with detailed information on formulation, and in some cases, prepared the finished formulation so that our migration studies would accurately evaluate the degree of migration.

In the next series of tables I have selected representative data merely to give an indication of the degree of migration. Table 4 shows the typical migration of rosin size to

Table 4. --Typical migration of rosin size 1/

Type food	Temp.	Time	Migration
		Days	p. p. m.
Ice cream	Freezer	28	.1
Green beans	Freezer	28	.1
Chicken	Refrig.	3	3.2
Sausage	Refrig.	5	52.7
Butter	Refrig.	7	10.7
"Puffedrice"	Room	7	4.8
Sugar	Room	7	.8

1/ 2.5 percent pale rosin size in paper.

food. In this table, I have shown the analyses in foods which have been stored for reasonable times at reasonable temperatures in contact with typical commercial paper containing 2.5 percent radioactive rosin size. It is obvious that migration is a function of temperature and degree of fat in the food. In table 5

Table 5. --Typical migration of rosin ester from lacquer coating 1/

Type food	Temp.	Time	Migration
		Days	P. p. m.
Aqueous	Refrig.	14	.1
Fatty	Refrig.	14	47
Aqueous	Room	14	.8
Fatty	Room	14	72

1/ Containing 20-percent Hercolyn D,

I have summarized data for aqueous and fatty foods at refrigerator and room temperatures for a commercial nitrocellulose lacquer coating on paper, containing 20 percent Hercolyn D in the coating. This particular experiment was conducted both with tritium tagged Hercolyn D and C^{14} tagged Hercolyn D, (C^{14} in the methanol radical). Again migration to fatty foods is the most significant.

Table 6 shows the migration from paper with a wax coating that has been modified with

Table 6. --Typical migration of rosin ester from wax coatings 1/

Type food	Temp.	Time	Migration
		Days	P. p. m.
Aqueous	Refrig.	14	1.4
Aqueous	Room	14	3.0
Aqueous	Warehouse	14	11.6

1/ Containing 10-percent Staybelite Ester 10.

10 percent Staybelite Ester 10. No fatty foods were studied because such foods are not ordinarily packaged in this type of paper. These data reveal the marked effect of temperature on the degree migration.

Table 7 shows similar data for aqueous and fatty food exposed to paper containing no

Table 7. --Typical migration of rosin ester from adhesives 1/

Type food	Temp.	Time	Migration
		Days	P. p. m.
Aqueous	Refrig.	7	.6
Fatty	Refrig.	7	13
Aqueous	Room	7	1.2
Fatty	Room	7	13

1/ Containing 50-percent Staybelite Ester 10; 95-percent overlap.

radioactive rosin except in the adhesive used for sealing edges. The adhesive contained 50 percent Staybelite Ester 10 as the tackifying agent. Only 5 percent of the adhesive was in direct contact with the food. High temperature and fatty foods result in the highest level of migration.

Table 8 shows the migration, or extraction, or a rosin ester from chewing gum when

Table 8. --Typical migration from chewing gum[1/]

Mastication	Time	Migration
	Hrs.	P. p. m. to total diet
Machine	1	.7
	5	.9
Human	1	.3
	2	.4

1/ Gum base containing 20-percent Hercolyn D.

used as a softening agent in the masticatory substance. This particular gum base contained 20 percent Hercolyn D and the gum base represented 20 percent of the finished chewing gum. The migration figures are calculated on a total diet basis (1 kilogram of dry food per day) to permit comparison with other migration data and assuming a maximum chewing of 1 pack a day. The data show a low level of migration both from the mastication machine, which was a laboratory double-armed kneader, and from actual human mastication of the radioactive gum and expectoration of saliva.

Table 9 summarizes all of the migration studies and shows the average migration to the two categories of foods from the five major applications of rosin products.

Table 9. --Average migration of rosin products (Typical conditions of use and storage)

Application	Aqueous foods	Fatty foods
	P. p. m.	P. p. m.
Rosin sizing	1.5	32
Lacquer coatings	.5	24
Wax coatings	1.0	--
Adhesives	.4	5
Chewing gum	.5	--

The facts are now available on the degree of migration to food resulting from the use of rosin products. The facts are also available on the toxicity of these products to experimental animals. Table 10 shows the comparison of toxicity with our best estimate of the amount of rosin contributed to the diet of humans. A minimum of a 200-fold margin of safety exists.

Table 10. --Comparison of migration results with toxicity

Migration to total diet of man	5 to 10 p. p. m.
Safe level in total diet of rats and dogs	2,000 to 10,000 p. p. m.

I have tried to summarize the investigations Hercules has conducted to demonstrate the safety of rosin products in several of their major uses. These data have been submitted to the Food and Drug Administration and have served as the major basis for the proposed regulation permitting their uses in these applications. We are confident that the Food and Drug Administration will agree that the use of these products involves no risk to the health of the consumer.

SESSION IV - PANEL DISCUSSION

F. R. Gates, Chairman

CONCLUSION OF CONFERENCE

The Conference concluded with a panel discussion on problems facing the naval stores industry. The session was chaired by F. R. Gates, Union Bag-Camp Paper Corp., New York, N. Y. Members of the panel and the areas they covered are: C. H. Horst, Guignon & Green, Inc., New York, N. Y., "Marketing;" E. L. Patton, The Langdale Co., Valdosta, Ga., "Manufacturing;" E. G. Crum, Hercules Powder Co., Wilmington, Del., "Utilization;" G. W. Varn, Varn Trading Co., Jacksonville, Fla., and J. S. Laws, Filtered Rosin Products Co., Baxley, Ga., "Quality and Raw Materials;" and J. R. Durland, Monsanto Chemical Co., St. Louis, Mo., "Research."

Judge Harley Langdale, President of the American Turpentine Farmers Association, in his closing remarks thanked the participants; and, in behalf of the naval stores industry, expressed appreciation for the government research program.

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ATTENDANCE OF PERSONNEL FROM THE SOUTHERN UTILIZATION RESEARCH AND DEVELOPMENT DIVISION FOR AT LEAST ONE SESSION OF THE MEETING

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Fisher, C. H., Director, New Orleans, La.

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