TALL OIL FATTY ACIDS

IN ANIMAL FEED

JAMES RUSSELL

JUNE 1989

A LITERATURE SEARCH PREPARED FOR

THE PULP CHEMICALS ASSOCIATION INC.

TALL OIL FATTY ACIDS IN ANIMAL FEED

Summary

This study was carried out at the request of the Executive Committee of the Pulp Chemicals Association to establish the status of the regulations governing the use of tall oil fatty acids in animal feed and to summarize the experimental work that had been done in this area. This study would provide the background knowledge required in order to establish the type and extent of feeding studies required (if any) for tall oil fatty acid to be acceptable to the animal feed market.

Literature governing federal regulation and feeding studies were made and the key findings summarized. It was concluded that tall oil fatty acid, no matter what the quality,is not approved by the FDA for use in animal food. It was also concluded that the experimental studies published in the literature show sufficient detrimental effects that the FDA approval will not be obtained without some feeding studies. For high quality fatty acids, the feeding studies could be expected to be much shorter (say 90 days) than for lower quality fatty acids (say 2 years).

It is recommended that if the members of the Pulp Chemicals Association wish to pursue the development of this potentially large market for tall oil fatty acids, the findings of this report be reviewed with the FDA to establish the actual feeding studies required.

However, based on the author's experience it is recommended that no further action be taken at this time. It is likely that only high quality tall oil fatty acids could be approved for use in animal food without extensive and expensive feeding studies and more profitable markets for these products now exist.

The animal feed market might be profitable for lower quality fatty acids but long term feeding studies would be required by the FDA. In addition, if products were approved, the FDA would probably establish detailed specifications on the composition of the approved materials. Thus, the testing and certification needed to assure compliance with these specifications would be difficult to justify for such low cost and variable composition products.

TALL OIL FATTY ACIDS IN ANIMAL FOODS

The possibility that the animal feed market would be an attractive outlet for tall oil fatty acid has been discussed intermittently for many years. Although limited quantities of tall oil fatty acids are thought to have been used in this market, it has never become an established market.

In order to obtain a better understanding of the regulations governing this end use and any relevant experimental work, the Pulp Chemicals Association commissioned this literature search. Thus the objectives of this study were to 1) establish the regulations governing the use of tall oil fatty acids in animal food, 2) identify and summarize any feeding or toxicity studies that have been made on tall oil fatty acids and 3) make recommendations regarding which, if any, feeding studies might be required to obtain the necessary federal approval for the use of tall oil fatty acids in animal feed.

The study carried out consisted of two distinct parts; first a survey of pertinent federal regulations and second, a literature survey of published toxicity data and animal feeding studies.

FEDERAL REGULATIONS

The FDA's regulations regarding the use of fatty acids in human food are given in Title 21 CFR Section 172.860. It states that the fatty acids should be

"manufactured from fats and oils from edible sources", should not contain more than 2% unsaponifiable matter and should be free of chick edema factor (pesticide residues). The only tall oil fatty acid derived product approved for direct addition to feed is oleic acid derived from tall oil fatty acids. This is listed in Title 21 CFR Section 172.862 and states that the product should contain $< 0.5\%$ unsaps and $< 0.1\%$ rosin acids as well as being free of chick edema factor. Thus the regulations governing the use of fatty acids in human food are strict and do not permit the use of conventional tall oil fatty acids.

The FDA's regulations regarding animal feeds are listed in Title 21 CFR Sub Chapter E, Parts 500 to 589. Part 570.3 states that the term "food" includes both human and animal food as well as substances migrating to food from food contact articles and Part 509.4 regulates the level to which such a poisonous or deleterious substance may be used. Thus FDA approval for use of any substance in animal feed is required, just as it is for use in human food.

Title 21 CFR, Part 573 lists the food additives permitted in food and drinking water of animals and Part 582 and 584 list GRAS (generally regarded as safe substances) for use in animal feed. Tall oil fatty acids is not listed under either of these regulations. Thus tall oil fatty acids would not appear to be approved for use in animal feed. However, in 1981 Dr. George Graber, Director

of the FDA's Division of Animal Feeds, indicated that (see attachment #1) the FDA had no objection to the use of TOFA in animal feeds providing the rosin acid level was less than 1% and the unsaponifiable matter content of less than 2%. He did indicate that the FDA was not completely satisfied as to the safety of TOFA for feeding purposes.

More recently (see attachment #2) Dr. Graber announced that the FDA were reversing their previously announced position regarding the use of TOFA and would not permit its use until "a food additive regulation is published based on data in a petition showing that the product is safe as an animal feed ingredient".

To summarize, therefore, the current status is that TOFA, no matter what the quality, is not approved for use in animal feed. A formal petition to the FDA citing toxicity, feeding and related studies etc., demonstrating that TOFA is safe as an animal feed ingredient would be required in order to receive approval.

PUBLISHED TOXICITY AND FEEDING STUDIES

A moderate amount of work has been published on both toxicity studies and feeding studies on tall oil fatty acids and its derivatives. Unfortunately in many cases the quality of the TOFA used was not defined and a variety of control materials were used. In other cases, derivatives of TOFA were tested, not TOFA itself. Thus precise comparisons of published date cannot be drawn and only general trends can be established.

Probably the most extensive related study published is the "Scientific Literature Reviews on Generally Regarded as Safe (GRAS) Feed Ingredients - Tall Oil".[1] This was prepared for the FDA in 1973 and includes data on whole tall oil and rosin as well as tall oil fatty acids. A copy of the title page is included in the appendix to this report (attachment #3). Based on this report, crude tall oil was granted GRAS approval for use in packaging of dry foods in cotton materials. Approval for this very limited use was re-affirmed in 1986.[2]

Toxicity Studies

The LD50rats for TOFA is reported to be greater than 10,000mg/Kg i.e., essentially non-toxic.[3] Similar high LD50s are reported for many esters of epoxydized tall oil fatty acids indicating that they too are essentially non-toxic.[4] No aquatic toxicity data has been published in tall oil fatty acid but it is reported[5] that the sodium salts of tall oil fatty acid have an LC50 of 5mg/Kg indicating a moderately high toxicity to fish.

Thus as with rosin, tall oil fatty acids appear to be non-toxic to animals but more toxic to fish.

Feeding Studies - Rats

Two detailed but unpublished feeding studies using tall oil fatty acids were carried out by a PCA member company in the mid to late 1970s. In these studies, a good quality United States tall oil fatty acid (Rosin acid $<$ 0.5%) was fed to rats in a multi-generation reproduction system at 5% and 10% of their diets. Control

groups were fed 5% and 10% food grade oleic acid as well as normal diets. The data demonstrated that the tall oil fatty acid did not affect the reproduction physiology of the rat and there were no significant differences between the offspring of the rats fed tall oil fatty acids and the controls. It must be remembered that these tests were carried out using a high quality tall oil fatty acid.

Probably the most extensive feeding tests carried out were made by Seppanen and his co-workers[6,7] using Finnish tall oil fatty acids. The material used was of lower quality than that in the previously described experiment, as it contained 2% resin acids and 3% unsaponifiable matter. In addition to testing the free fatty acids they tested ethyl esters and glycerol esters of the fatty acids. The objective of their work was to establish whether an acceptable quality of margarine could be developed from tall oil fatty acids. Consequently growth, food consumption, reproduction and longevity experiments were carried out using rats which were fed diets containing test materials at 15%, 30%, and 60% of total calories.

Their conclusions were "that tall oil fatty acids contained some toxic factor, the effects of which were a retardation of growth, disorders of the skin and fur and even death when the tall oil fatty acid content of the diet was 60 cal%". They also concluded that refining

the fatty acids to reduce the rosin acid and unsaponifiable matter, weakened this toxic factor as did the conversion to ethyl and glyceryl esters and hydrogenation. In fact, margarine made from the glyceryl esters of hydrogenated tall oil fatty acids, had a similar nutritional value to commercial butter and margarine.

Seppanen concluded that the toxic factor in Finnish tall oil fatty acids was produced "from the highly unsaturated fatty acids in the tall oil by the elevated temperatures used in the pulping and tall oil distillation processes." Indications were that the specific unsaturated acid was cis 5, 9, 12 octadecatrienoic acid. However, separate experiments were unable to confirm this.

Although the overall conclusions of this Finnish study conflicts with that of the U.S. study, there are many differences in the studies that would account for the conflict. The U.S. study used high quality U.S. tall oil fatty acids, essentially free of triunsaturated acids. The Finnish study used lower quality tall oil fatty acids containing moderate levels (up to 10%) of highly unsaturated acids. The feeding levels were also different. Thus the U.S. tests were carried out at 5 and 10% of the diet calories whereas the Finnish tests were all at higher levels i.e., 15, 30 and 60%.

The deaths reported by Seppanen however, may not have been due to the presence of a toxic material in the tall oil fatty acids. The rats may have refused to eat

the diet high in tall oil fatty acids and actually starved to death. Refusal to eat and subsequent loss in weight is not uncommon in animal feeding studies involving naval stores products.[8]

It should be recognized also that the objectives of the studies were different. The U.S. study was aimed at establishing any reproductive affect whereas the Finnish study was concerned with nutritional effects. Overall however, the results indicate that good quality tall oil fatty acid, essentially free of triple unsaturated fatty acids fed at a level of 10% in the diet would not be harmful.

Feeding Studies - Chickens

M.and V.Antila and their co-workers[9] have studied the use of tall oil fatty acid and its derivatives, especially the ethyl ester as an ingredient in chicken feed. Their primary objective was the utilization of the ethyl esters of tall oil fatty acid as a nutritional supplement, as both tall oil fatty acids and ethyl alcohol were readily available in Finland. They studied the effect of the ester on egg production, fertility, hatchability and composition of the fat content of both eggs and chicken meat. The levels used were 5% and 10% of the esters in the basic diet.

Antila and his co-workers ran three separate feeding studies and, although the results were not consistent, they concluded that the presence of tall oil fatty acid

ester was somewhat detrimental to egg production. They also concluded that fertility and hatchability were not impaired.

However, marked changes in the fatty acid composition of the egg yolk were found. The oleic acid content of the yolk increased and the palmitic, stearic and linoleic acids content decreased when the chickens were fed the diet containing the ester. In addition, the tall oil fatty acid ester caused a reduction in egg weight and "impaired the baking characteristics of the eggs." In contrast to the change in composition of the egg yolk, the workers found no difference in the fatty acid composition of the meat of the chicken.

Cattle

Antila and co-workers[10, 11] have also studied the use of tall oil fatty acids and particularly its ethyl esters as an ingredient in animal fodder. In this study, cows were given the ethyl esters of tall oil fatty acids for about 45 days at levels of 3% and 4% in their diet. The yield of milk, milk fat and protein in the milk were measured.

It was concluded that the milk yield and protein were unaffected by the presence of ester in the diet but the milk fat content decreased at the 4% level but not the 3% level. However, the iodine number of the milk fat increased significantly in both tests indicating that the presence of tall oil fatty acid esters in the diet was changing the composition of the milk fat. Analysis

indicated that the palmitic acid content of the milk fat was decreased and its oleic acid content increased.

Conclusions

Overall,the conclusions reached based on the limited studies carried out is that high quality tall oil fatty acid derived from crude tall oil from the South Eastern United States would not cause any harmful effects if used in animal feed. It would appear that such good quality products could be substituted for soyabean oil or other food grade fatty products currently used in animal feed. However, if this market was to be pursued, approval would have to be obtained from the FDA via the filing of a petition with the FDA. Feeding studies may well be required but for high quality fatty acids,($<$ 1% rosin acids and $<$1% unsaps) it is possible that these feeding studies may not be extensive (say 90 days). The FDA would most likely establish firm specifications on the quality of the fatty acid permitted and would require that the product be specified to be free of chick edema factor.

The conclusions regarding the potential use of lower grade fatty acids are less encouraging. The limited data available indicates that average quality Scandinavian tall oil fatty acids contain some ingredient, whose identity is not confirmed, that is either toxic or extremely unpalatable to animals. Possibly, ways exist to improve the palatability of these grades of tall oil fatty acids but it seems unlikely that the FDA would approve the use

of lower quality tall oil fatty acids, either U.S. or Scandanavian, without extensive feeding studies (say 2 years).

Also, in view of any deleterious effects possibly being associated with the minor components of the tall oil fatty acid, it seems likely that the FDA would insist that any product used in animal food would be required to meet well defined specifications.

It should also be recognized that apart from any possible toxic effects, the presence of tall oil fatty acids in animal feed,changes the composition of milk fat and egg yolks. Such changes may or may not be detrimental to the products but they do appear to be real. It is likely, however, at the low concentrations where tall oil fatty acids would be used that these effects would be negligible.

Recommendations

It is recommended that the members of the Executive Committee review this report with a view to establishing future actions. Possibe actions are:

1) Review this report with the FDA and request an opinion regarding the type of feeding studies required in order to file a petition.
2) Obtain an opinion from legal counsel regarding the type of feeding studies required.
3) Take no further action at this time but retain the report for use at a later date.

However, based on the author's experience it is recommended that no further action be taken at this time. It is likely that only high quality tall oil fatty acids could be approved for use in animal food without extensive and expensive feeding studies and more profitable markets for these products now exist.

The animal feed market might be profitable for lower quality fatty acids but long term feeding studies would be required by the FDA. In addition, if products were approved, the FDA would probably establish detailed specifications on the composition of the approved materials. Thus, the testing and certification needed to assure compliance with these specifications would be difficult to justify for such low cost and variable composition products.

REFERENCES

1. Scientific Literature Reviews on Generally Regarded as Safe Feed Ingredients - Tall Oil. Tracor -Jitco Incorporated, Report #FDABF-GRAS-199. Prepared for the Food & Drug Administration, December 1973.

2. Federal Register, 51 88 page 16830, 1986. (May 7 issue).

3. Material Safety Data Sheet, FA3 Tall Oil Fatty Acids, Arizona Chemical Company, Panama City, Florida.

4. Weil, C.S., Condra, N., Haun, C., Striegel, J.A., Amer. Ind. Hyg. Assoc. J. 24(4), 305,(1963).

5. Van Horn, W.M., Anderson, J.B., Katz, M.; Trans. Amer. Fish Soc. 79, 55, (1949).

6. Seppanen, R., Roine, P., Antila, M.; Suomen Kemistilehti B36, p 221-224 (1963).

7. Seppanen, R.; Ann. Acad. Sci. Fenn. Ser. A II Chem. 144 p 7-85 (1969).

8. See for example Domanski, J.J., Chapter 27, "Toxicology" in"Naval Stores, Production, Chemistry, Utilization". Pulp Chemicals Association (1989).

9. Antila, V., Oittila, R., Ring, O., Uotila, M., Antila,M.; Acta. Agr. Scand. 15 (1) 16-24 (1965).

10. Antila, V., Karkkainen, V.J., Ring, O., Antila, M.; Acta. Agr. Scand. XIII 195-204 (1963).

11. Antila, V.: Fat. Oil Chem. Scand. Symp. Proc. p 271-7 (1967).

APPENDIX

1. Copy of 1981 informal FDA opinion on tall oil fatty acids.
2. Copy of 1989 FDA statement on tall oil fatty acids.
3. Material Safety Data Sheet, FA 3 Tall Oil Fatty Acids, Arizona Chemical Company.
4. Copy of cover pages of reference #1.
5. Copy of abstract of reference #7.
6. Organizational Chart of the FDA's Center for Veterinary Medicine (1988.)

TALL OIL FATTY ACIDS GIVEN INFORMAL BVM OK FOR FEED USE

The Food and Drug Administration on Dec. 31 issued an informal opinion to International Patented Feed Corporation expressing no objection to use in feed of a fat product, the main fatty acids being derived from tall oil.

". . . We do not object at this time to the incorporation of the fat product as described. . . in your line of animal feeds," Dr. George Graber, Director of the Division of Animal Feeds in the Bureau of Veterinary Medicine, wrote. He noted that "several wood-derived products have been and are currently being fed to animals and to the best of our knowledge without any known adverse effects."

This was the second issuance of a BVM no-objection letter under a newly-adopted policy. The Bureau earlier expressed no objection to use of polysorbate 80 as an emulsifier in vitamin and mineral premixes (See FOOD CHEMICAL NEWS, Dec. 21, Page 25).

Graber told International Patented Feed that BVM is "considering a more in-depth look at the types of wood-derived products used as food sources for animals." He wrote:

> "We appreciate the information you have already supplied and look forward to receiving any additional information you or your colleagues might have. In your letter of Dec. 7, you indicated an interest in repeating some of the research done in the 1950s and 1960s. We would find such data of great interest."

In expressing no objection to the firm's Chem-U-Lator line of animal feeds, Graber questioned whether the product "is most appropriately, for safety reasons," described by the American Association of Feed Control Officials definition of "fat product, feed grade." The FDA-er noted that this definition specifies the minimum percentage of total fatty acid, expressing the view that "the safety of the product can best be assured by specifying the 'maximum' percent of tall oil fatty acids." He wrote that BVM will notify AAFCO of its position and will "gladly work with you in developing a more suitable definition."

The International Patented Feed product, the letter said, "will contain at least 95% oleic and linoleic acids, either free or as methyl esters, plus rosin acids (less than 1%), unsaponifiable matter (less than 2%), BHT (300 p.p.m.), and ethoxyquin (0.3%)."

Expressing some apparent reservations, Graber said the "safety of tall oil fatty acids as direct food additives has never been established," noting that the only direct additive clearance is for purified oleic acid separated from refined tall oil fatty acids under specifications and conditions of use described in the Food Additive Order for oleic acid derived from tall oil fatty acids (§172.862). He wrote:

> "This review. . . has not been an easy task. For instance, it took many submissions from you to provide the type of information/data we considered necessary to make an assessment. Regardless, once compiled, we were not overly impressed with the scientific data from the point of it being current and supportive as to the safety of the fat product. To broaden our data base, computer searches were conducted plus several experts were consulted. In spite of this additional information, we were not totally satisfied as to the safety of this product for feeding purposes."

ATTACHMENT #1

The Congressman suggested that the Post "reconsider" its position, saying:

> "The FDA lacks jurisdiction over many food products, such as meat and beer. The Department of Agriculture does a better job on the labeling of foods under its jurisdiction than FDA does. Except for reduced-calorie food, the FDA allows 'Lite' to be used indiscriminately. The FDA allows virtually any word to be in the name or trademark of a product, even if the name is misleading. The FDA does not require comparative labeling so that shoppers can see the differences between 'Lite' and regular products."

■

TALL OIL FATTY ACIDS FEED USE BARRED BY FDA

The Food and Drug Administration has "reversed its position regarding the use of tall oil fatty acids (TOFAs) in animal feeds," and will not permit such use until "a food additive regulation is published based on data in a Petition showing that the product is safe as an animal feed ingredient," Dr. George Graber, Director of the Division of Animal Feeds in FDA's Center for Veterinary Medicine, said in a March 2 "update" speech before the National Feed Ingredients Association in Dallas, Tex.

He said the American Association of Feed Control Officials followed FDA's lead in recently voting to "remove the definition of TOFAs from its Official Publication," adding that the industry has been notified of the prohibition.

Graber also disclosed that CVM is "looking once again at the safety of deodorizer distillates as feed ingredients," noting that an old agency proposal to ban deodorizer distillates from feed was "never finalized in part because our database was not current." He said a literature search is now being conducted by CVM "for purposes of updating the database."

Graber disclosed that "regulatory action is being considered based on recent investigations against several companies involved in illegal diversion of unacceptable fats and oils."

Discussing diversion of industrial-grade fats and oils to the feed industry, Graber said, "In some cases, the illegal product, usually a blend, is presented as being feed grade, whatever that means, and, as such, no questions are being asked about its composition other than nutritional specifications." Under this arrangement, he added, "dilution is considered the solution except when the illegal product is uncovered and then such activity becomes subject to regulatory action."

Noting a problem of lack of uniformity of terminology for fats and oils, the CVM official disclosed that an AAFCO task force is standardizing the terminology.

Generic Animal Drug Law Expected to Increase MFA Amendments

Graber predicted that the new generic animal drug law is expected to result in an "increase in amendments to existing Medicated Feed Application (MFA) approvals," saying that the number of Type A medicated articles "is likely to increase significantly."

Although abbreviated New Animal Drug Applications (ANADAs) cannot be approved under the new statute until January 1991, Graber said "there really

ATTACHMENT #3

MATERIAL SAFETY DATA

ARIZONA CHEMICAL COMPANY
1001 EAST BUSINESS HWY 98
PANAMA CITY, FLORIDA 32401

MSDS NO.: 1258-03
DATE: 4/1/88
EMERGENCY PHONE: (904)785-8521
INFORMATION PHONE: (904)785-6700

PRODUCT IDENTIFICATION

TRADE NAME: ACINTOL FA-3

TSCA CAS NO.: 61790-12-3

SYNONYMS: TALL OIL FATTY ACID

CHEMICAL FAMILY: FATTY ACIDS AND ROSIN ACIDS

MOLECULAR WEIGHT: MIXTURE

MOLECULAR FORMULA: MIXTURE

HAZARDOUS COMPONENT

COMPONENT	%	CAS NO.	TLV	STEL

NO PERMISSABLE EXPOSURE LIMITS HAVE BEEN ESTABLISHED BY OSHA

REFERENCE: ACGIH

WARNING: SEE SPECIAL PRECAUTIONS

PHYSICAL CHARACTERISTICS

MELTING POINT: N/A BOILING POINT: OVER 500F VOLATILES: NEG

WATER SOLUBILITY: NEG SPECIFIC GRAVITY (WATER = 1): 0.9

VAPOR PRESSURE, 20C NEG mm Hg: VAPOR DENSITY (AIR = 1): NOT AVAILABLE

APPEARANCE AND ODOR: Yellow to brown oil; vegetable oil odor

FIRE AND EXPLOSION

FLASH POINT (CLOSED CUP) 400 F: FLAMMABLE LIMITS, LEL N/A% UEL N/A%

NFPA RATING: HEALTH 0 : FIRE 1 : REACTIVITY 0

FIRE FIGHTING: Use water spray, carbon dioxide or dry chemical to extinguish fires. Wear self-contained, positive pressure breathing apparatus and full firefighting protective clothing. Use water to keep containers cool.

REACTIVITY

STABILITY - Stable : CONDITIONS TO AVOID - None Known

POLYMERIZATION - Will Not Occur : CONDITIONS TO AVOID - None Known

HAZARDOUS DECOMPOSITION PRODUCTS: None other than normal products of combustion

HEALTH HAZARDS

EFFECTS OF OVEREXPOSURE: Acute oral (rat) LD50 values for pale tall oil rosin and tall oil fatty acids are 7,600 mg/kg and greater than 10,000 mg/kg, respectively. Aspiration of liquid may cause pneumonitis. Repeated dermal contact may cause skin sensitization.

FIRST AID: If tall oil is swallowed, do not induce vomiting. In case of skin contact, wash affected areas of skin with soap and water. Do not reuse clothing without laundering.

CARCINOGENICITY LISTING: None

SAFE HANDLING AND USE

SPILL OR LEAK PROCEDURES: Spills of this material are very slippery. Cover spills with some inert absorbent material and scoop into a container. Wash area thoroughly with water. Repeat if slipperiness remains.

SPECIAL PRECAUTIONS: As with all unsaturated fats and oils, some porous materials such as rags, paper, insulation or clay when wetted with this product may undergo spontaneous combustion. Keep such wetted materials well ventilated to prevent possible heat build-up.

WASTE DISPOSAL: Disposal must be made in accordance with applicable governmental regulation.

CONTROL MEASURES

EXPOSURE CONTROL: Engineering controls are usually not necessary if good hygiene practices are strictly followed. Respiratory protection is generally not required during normal operations. Wear the following to prevent skin contact; work pants, long sleeve work shirt and work gloves. Where there is danger of eye contact, wear splash proof goggles

THE INFORMATION CONTAINED IN THIS MATERIAL SAFETY DATA SHEET IS BASED ON THE BEST DATA OF WHICH WE ARE AWARE AND IS BELIEVED CORRECT AS OF THE DATE HEREOF. SINCE THE USE OF THIS INFORMATION AND THE CONDITIONS OF USE OF THIS PRODUCT ARE NOT WITHIN OUR CONTROL, IT IS THE USER'S OBLIGATION TO DETERMINE THE CONDITIONS FOR SAFE USE OF THIS PRODUCT.

ATTACHMENT #4

PB-228 556

SCIENTIFIC LITERATURE REVIEWS ON GENERALLY RECOGNIZED AS SAFE (GRAS) FOOD INGREDIENTS- TALL OIL

TRACOR-JITCO, INCORPORATED

PREPARED FOR

FOOD AND DRUG ADMINISTRATION

DECEMBER 1973

DISTRIBUTED BY:

NTIS

National Technical Information Service
U. S. DEPARTMENT OF COMMERCE

ATTACHMENT #4 CONTINUED

BIBLIOGRAPHIC DATA SHEET	1. Report No. FDABF-GRAS-199	2.	PB 228 556

4. Title and Subtitle

Scientific Literature Reviews on Generally Recognized As Safe (GRAS) Food Ingredients - Tall Oil

5. Report Date: December 1973

6.

7. Author(s)

8. Performing Organization Rept. No.

9. Performing Organization Name and Address

Tracor-Jitco, Inc.
1300 E. Gude Drive
Rockville, Maryland 20851

10. Project/Task/Work Unit No.

11. Contract/Grant No.: FDA 72-100

12. Sponsoring Organization Name and Address

U.S. Food and Drug Administration
200 "C" Street, S.W.
Washington, D.C. 20204

13. Type of Report & Period Covered: Final-1920 to 1973

14.

15. Supplementary Notes

16. Abstracts

The Scientific Literature Review summarizes the available scientific literature from 1920 to 1973 related to the safety of tall oil as a food ingredient. Chemical Information, biological data, and biochemical aspects of tall oil are given in a 82 page summary containing 177 references.

17. Key Words and Document Analysis. 17a. Descriptors

17b. Identifiers/Open-Ended Terms

17c. COSATI Field/Group

18. Availability Statement: Release unlimited

19. Security Class (This Report): UNCLASSIFIED

20. Security Class (This Page): UNCLASSIFIED

21. No. of Pages

22. Price

ATTACHMENT #5

Abstract

The nutritional properties of tall oil fatty acids have been investigated using rats as experimental animals. The effects of *tall* oil fatty acid *distillate* and its ethyl and glyceryl esters on the growth rate, food consumption, reproduction and longevity of the rats, on the absorbability and on the fatty acid compositions of adipose tissue, plasma, liver and fecal lipid fractions were investigated.

Mainly weanling male rats were used in the growth and absorbability experiments and both male and female rats in long-term and reproduction experiments. The organs from which lipids were extracted for the determination of fatty acid compositions were from full-grown rats. The semisynthetic diets that were given to the animals contained fat at levels of 15, 30 or 60% of total calories.

The results indicated that tall oil fatty acids contain some toxic factor, the effects of which were a retardation of growth, disorders of the skin and fur, and even death when the tall oil fatty acid content of the diet was 60 cal %.

When more effectively refined tall oil glycerides were fed, the growth-retarding effect of the toxic factor was clearly weaker. Hydrogenation of tall oil fatty acid glycerides apparently improved the nutritional properties of the product.

Histopathological investigations of animals fed hydrogenated tall oil fatty acid glycerides revealed a couple of cases of thyreoiditis and a few cases of degenerated liver parenchyma and swollen tubular cells, which were, however, relatively minor.

Determination of the absorbability of the tall oil fatty acid preparations tested indicated that they were absorbed to the extent of 93—96%.

The growth-retarding factor is evidently produced from the highly unsaturated fatty acids in the tall oil by the elevated temperatures used in the pulping and tall oil distillation processes.

Gas-chromatographic determinations of the fatty acid compositions of the adipose tissue, plasma, liver and fecal lipids from rats given tall oil fatty acid distillate showed that *cis*-5,9,12-octadecatrienoic acid, which is a typical tall oil fatty acid, accumulated in the fecal lipids. Only minor amounts of this acid were detected in the organ lipids.

I. INTRODUCTION

Tall oil, which is a by-product of the sulphate pulp manufacturing process, is a mixture of resin and fatty acids. As the cellulose industry has expanded, the amount of crude tall oil produced has risen appreciably in the last few years. A large part is exported in crude and refined grades. The crude tall oil can be separated into resin acid and fatty acid fractions by distillation. The resin acids are used almost entirely by the domestic

(Area Code 202)

Toxicological Review Division
Director Samuel Shibko 1054 MES 472-5834
Additives Eval Br Chf Garfield N Biddie 1407A MES 472-5701
Standards & Monitoring Eval Br Chf Charles Kokoski 1054 MES 472-5767

Toxicological Studies Division
Director Sidney Green 6836 FB8 245-1195
Animal Resources Br Chf Jay Burke 5050 FB8 245-1369
Dermal & Ocular Toxicology Br Chf Andrija Kornhauser 6828 FB8 245-1195
General & Molecular Toxicology Br Chf Carol Mapes 6828 FB8 . . 245-1195
Genetics Toxicology Br Chf Virginia C Dunkel 1476 FB8 245-1229
Metabolism Br Chf Eugene Miller 21 BRF . . . . . (301) 344-4000

CENTER FOR VETERINARY MEDICINE

(Area Code 301)

Director Gerald B Guest 7-57 PKLN 443-3450
Dep Director Richard H Teske 7-57 PKLN 443-3450
Eq Empl Oppor Specialist Dwayne Jones 8-96 PKLN 443-4940

Office of Management
Director Monte B Nichol 7-67 PKLN 443-4465
Dep Director J Kirk Winkle 7-67 PKLN 443-2795
Administrative Mgmt Staff Chf Barbara Leach 7-67 PKLN 443-2726
Planning Eval & Fin'l Mgmt Staff Chf Carol Gray 7-89 PKLN 443-1573

Office of New Animal Drug Evaluation

Director Richard B Talbot 6B-03 PKLN 443-4313
Deputy Director for:
Human Food Safety & Consultative Svcs Robert Livingston 6B-03 PKLN 443-4313
Therapeutic & Production Drug Review Robert Livingston (Actg) 6B-03 PKLN 443-4313

Biometrics Informatics and Environmental Sciences Division
Director (Vacant) 8-81 PKLN 443-2280
Biometrics & Informatics Br Chf James Colaianne 6B-21 PKLN . . 443-1580
Data Systems Br Chf Henry Pykosh 7-58 PKLN 443-1290
Environmental Science Br Chf John C Matheson 8-70 PKLN 443-1880

Manufacturing and Residue Chemistry Division
Director Susan Fitzpatrick 8-81 PKLN 443-6971
Manufacturing & Quality Control Br Chf John R Markus 8-92 PKLN 443-3442
Residue Eval Br Chf Nicholas Weber 8-81 PKLN 443-6971

Production Drugs Division
Director Richard P Lehmann 6B-37 PKLN 443-3134
Ruminant Drugs Br Chf Jack Taylor 6B-37 PKLN 443-5247
Swine & Poultry Drugs Br Chf Lonnie Luther 6B-31 PKLN 443-4317

Therapeutic Drugs for Food Animals Division
Director Donald A Gable 6B-04 PKLN 443-1414
Antimicrobial Drugs Br Chf Charles Haines 6B-04 PKLN 443-3410
Antiparasitic & Physiological Drugs Br Chf Diane T McCrae 6B-04 PKLN 443-4913

Therapeutic Drugs for Non-Food Animals Division
Director Bob G Griffith 6B-24 PKLN 443-1963
Companion & Wildlife Drugs Br Chf Marsha K Larkins 6B-24 PKLN 443-3430
Equine & Antimicrobial Drugs Br Chf Sandra K Woods 6B-32 PKLN 443-3420

Toxicology Division
Director Alexander Apostolou 8-70 PKLN 443-5540
Antimicrobial & Antiparasitic Drugs Br Chf Thomas S Sulkowski (Actg) 8-70 PKLN 443-5540
Hormones & Pharmacological Agents Br Chf (Vacant) 8-70 PKLN 443-5540

Office of Science

(Area Code 301)

Director Norris E Alderson 8-89 PKLN 443-6510

Veterinary Medical Research Division
Director Robert D Furrow BLTV 344-2556
Dep Director Charlie J Barnes (Actg) BLTV 344-2556
Animal Nutrition & Biology Br Chf David Wagner BLTV 344-8500
Method Validations & Analytical Br Chf Michael H Thomas (Actg) BLTV 344-8500
Veterinary Pharmacology & Toxicology Br Chf Badaruddin Shaikh BLTV 344-2556

Office of Surveillance and Compliance

Director George A Mitchell 7B-31 PKLN 443-3400
Dep Director Gary J Dykstra 7B-31 PKLN 443-3400

Animal Feeds Division
Director George Graber 7B-45 PKLN 443-4438
Dep Director William D Price 7B-45 PKLN 443-4438
Feed Safety Br Chf Lea McGovern 7B-45 PKLN 443-5362
Petitions Review & Medicated Feeds Br Chf Woodrow Knight 7B-45 PKLN 443-3390

Compliance Division
Director Edward J Ballitch 7B-05 PKLN 443-3336
Bioresearch Monitoring Pgm Staff Chf Dorothy Pocurull (Actg) 7B-05 PKLN 443-0530
Case Guidance Br Chf Marie A Urban 7B-21 PKLN 443-2830
Petitions & Regulations Br Chf Robert S Brigham 7B-21 PKLN . . 443-6243

Surveillance Division
Director Andrew J Beaulieu 7B-08 PKLN 443-3044
Dep Director Howard Meyers 7B-08 PKLN 443-3044
Medical Review & Drug Listing Br Chf Vitolis E Vengris 7B-20 PKLN 443-3183
Post Approval Br Chf Mohammad I Sharar (Actg) 7B-20 PKLN . . 443-3183

Voluntary Compliance and Hearings Development Division
Director Philip J Frappaolo 7B-40 PKLN 443-4940
Industry Info Br Chf Gary E Stefan 7-89 PKLN 443-0830
Programs & Hearings Br Chf (Vacant) 7B-31 PKLN 443-4940
Tissue Residue Br Chf Joseph C Paige 7B-40 PKLN 443-6954

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH
County Road #3
Jefferson, AR 72079

Note: For FTS calls, dial 790 plus four-digit extension.

(Area Code 501)

Facsimile:
Commercial 541-4576
FTS 790-4576

(Area Code 501)

Director Ronald W Hart 23 Bg13 541-4517
Dep Director Arthur R Norris 22 Bg13 541-4516
Assoc Dir for Scientific Coord William P Allaben (Actg) 112 Bg15 541-4211
Biometry Staff Dir David W Gaylor 11B Bg15 541-4001

Office of Management
Associate Director Frank V Battle 124 Bg13 541-4130
Employee Assistance Pgm Ofcr Otis L Archer 104 Bg21 541-4473
Equal Empl Oppor Ofcr H O Gray 127 Bg13 541-4508
FDA Personnel Liaison Dick King 103 Bg21 541-4475
Training Ofcr Vicky Ross-Barsh 125 Bg13 541-4569
Planning & Eval Staff Dir Stephen A Douglas (Actg) 125A Bg13 541-4375
Facilities Engr'g & Maintenance Div Dir Robert A Davis 104 Bg13 541-4501