EVALUATION OF THE HEALTH ASPECTS
OITICICA OIL AS IT MAY MIGRATE TO FOODS
FROM PACKAGING MATERIALS AND OTHER CONTACT SURFACES

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Prepared for
Bureau of Foods
Food and Drug Administration
Department of Health and Human Services
Washington, D.C.

Contract No. FDA 223-78-2100
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Life Sciences Research Office
Federation of American Societies
for Experimental Biology
9650 Rockville Pike
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NOTICE

This report, one of a series concerning the health aspects of using the Generally Recognized as Safe (GRAS) or prior-sanctioned food substances as food ingredients is being made by the Federation of American Societies for Experimental Biology (FASEB) under contract no. 223-78-2100 with the Food and Drug Administration (FDA), U.S. Department of Health and Human Services. The Federation recognizes that the safety of GRAS substances is of national significance, and that its resources are particularly suited to marshaling the opinions of knowledgeable scientists to assist in these evaluations. The Life Sciences Research Office (LSRO), established by FASEB in 1962 to make scientific assessments in the biomedical sciences, is conducting these studies.

Qualified scientists were selected as consultants to review and evaluate the available information on each of the GRAS substances. These scientists, designated the Select Committee on GRAS Substances, were chosen for their experience and judgment with due consideration for balance and breadth in the appropriate professional disciplines. The Select Committee's evaluations are being made independently of FDA or any other group, governmental or nongovernmental. The Select Committee accepts responsibility for the content of each report. Members of the Select Committee who have contributed to this report are named in Section VII.

Tentative reports are made available to the public for review in the office of the Dockets Management Branch, Food and Drug Administration, after announcement in the Federal Register, and opportunity is provided for any interested person to appear before the Select Committee at a public hearing to make oral presentation of data, information, and views on the substances covered by the report. The data, information, and views presented at the hearing are considered by the Select Committee in reaching its final conclusions. Reports are approved by the Select Committee and the Director of LSRO, and subsequently reviewed and approved by the LSRO Advisory Committee (which consists of representatives of each constituent society of FASEB) under authority delegated by the Executive Committee of the Federation Board. Upon completion of these review procedures the reports are approved and transmitted to FDA by the Executive Director of FASEB.

While this is a report of the Federation of American Societies for Experimental Biology, it does not necessarily reflect the opinion of all of the individual members of its constituent societies.

Kenneth D. Fisher, Ph.D., Director
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I. INTRODUCTION

This report concerns the health aspects of using oiticica oil as a food ingredient. It has been based partly on the information contained in a scientific literature review (monograph) furnished by FDA (Rogers, 1978), which summarizes the world's scientific literature from 1920 through 1978. To ensure completeness and currency as of the date of this report this information has been supplemented by searches of over 30 scientific and statistical reference sources and compendia that are generally available; use of new, relevant books and reviews and the literature citations contained in them; consideration of current literature citations obtained through computer retrieval systems of the National Library of Medicine; searches for relevant data in the files of FDA; and by the combined knowledge and experience of members of the Select Committee and the LSRO staff. In addition, an announcement was made in the Federal Register of November 7, 1980 (45 FR 74056-74060) that opportunity would be provided for any interested person to appear before the Select Committee at a public hearing to make oral presentation of data, information, and views on the health aspects of using oiticica oil as a food ingredient. The Select Committee received no request for such a hearing.

As indicated in the Food, Drug, and Cosmetic Act [21 USC 321(s)], GRAS substances are exempt from the premarketing clearance that is required for food additives. It is stated in the Act and in the Code of Federal Regulations (Office of the Federal Register, 1980) [21 CFR 170.3 and 170.30] that GRAS means general recognition of safety by experts qualified by scientific training and experience to evaluate the safety of substances on the basis of scientific data derived from published literature. These sections of the Code also indicate that expert judgment is to be based on the evaluation of results of credible toxicological testing or, for those substances used in food prior to January 1, 1958, on a reasoned judgment founded in experience with common food use, and is to take into account reasonably anticipated patterns of consumption, cumulative effects in the diet, and safety factors appropriate for the utilization of animal experimentation data. FDA recognizes further [21 CFR 170.30] that it is impossible to provide assurance that any substance is absolutely safe for human consumption.

The Select Committee on GRAS Substances of LSRO evaluated this substance in full recognition of the foregoing provisions. In reaching its conclusions on safety, the Committee, in accordance with FDA's guidelines, relied primarily on the absence of substantive evidence of, or reasonable grounds to suspect, a significant risk to the public health. While the Committee realized that a conclusion based on such reasoned judgment was expected even in instances where the available information was qualitatively or quantitatively limited, it recognized that there could be instances where, in the judgment of the Committee, there were
insufficient data upon which to base a conclusion. The Committee anticipates that its conclusions will be reviewed as new information becomes available.

The LSRO Select Committee on GRAS Substances has reviewed the available information on oiticica oil and submits its interpretation and assessment in this report, which is intended for the use of FDA in determining the future status of this substance under the Federal Food, Drug, and Cosmetic Act.
II. BACKGROUND INFORMATION

Oiticica oil is obtained from the nuts of the tropical tree, *Licania rigida*, which is indigenous to the interior regions of Northern Brazil. *L. arborea* in Mexico and Central America and *L. crassifolia* in Surinam have been the source of similar oils (François, 1952). Limited attempts to cultivate the oil-producing trees in the United States and England have been unsuccessful (Jamieson, 1947).

The freshly expressed oil is a yellowish viscous liquid, which gradually solidifies within a few days to a pale green solid with the consistency of lard. Heating for 30–60 min at 210°-220°C renders the oil permanently liquid. Brazilian natives originally recovered the oil by boiling crushed nuts and decanting the floating oil. This inefficient method was replaced by the use of continuous screw or hydraulic presses to express the oil. Some mills recovered the residual oil from the presscake by extracting with petroleum ether or trichloroethylene.

Oiticica oil resembles tung oil in having much of its composition in the form of fatty acids with conjugated double bonds (Grummitt et al., 1965; Swern, 1964). The major source of this conjugated system in oiticica oil is licanic acid, whose structure was established by Brown and Farmer (1935) as: \( \text{CH}_3( \text{CH}_2)_3 \text{CH=CH=CH=CH} \text{(CH}_2 \text{)}_4 \text{CO(}\text{CH}_2\text{)}_2 \text{COOH} \). It has the distinction of being the first ketonic unsaturated fatty acid detected in natural products. According to early reports (Garmsen, 1950; Kaufmann and Baltes, 1936; Machado, 1938; Morrell and Davis, 1936) licanic acid was said to represent about 75% of the oil. However, more recent studies allowing improved analyses, suggest that these estimates are too high. Rheineck and Sampath (1971) found licanic acid to constitute 42% of the total fatty acid content of oiticica oil; oleic plus linoleic acids, 23%; eleostearic acid, 14%; stearic acid, 12%; palmitic acid, 7%; and an unidentified unsaturated hydroxy acid, 2%. Thus, unsaturated fatty acids comprised about 80% of the oil.

Although oiticica oil was used extensively by the coatings industry when tung oil was unavailable or expensive, currently all drying oils have difficulty competing with synthetic compositions such as vinyl, acrylic, epoxy, and urethane resins (Rheineck and Sampath, 1971). Because oiticica oil no longer enjoys an economic advantage over tung oil, its use in the paint and varnish industry also appears limited.

The Select Committee speculates that at one time oiticica oil may have been used in the preparation of can linings or for other food contact surfaces by the food industry. This assumption is based on two letters (Cassidy, 1960a,b), issued by the Food and Drug Administration in 1960 stating that oiticica oil was prior-sanctioned as a drying oil in formulating finished resins. No
information has been obtained on the specific nature or extent of this prior-sanctioned use. Following are the various regulated uses currently authorized by the Code of Federal Regulations (Office of the Federal Register, 1980):

21 CFR 175.300 As a drying oil in resinous polymeric coatings.

175.380 As an adjuvant substance in preparation of xylene-formaldehyde resins condensed with 4,4'-isopropylidene diphenol-epichlorhydrin epoxy resins.

175.390 Drying oil under zinc-silicon dioxide matrix coatings for food contact surfaces.

175.170 Component of paper and paperboard in contact with aqueous and fatty foods.

177.1210 Drying oil closures with sealing gaskets for food containers.

The Select Committee has been unable to obtain any evidence that oiticica oil is currently used in any manner that would contact foods, either through direct addition or by migration from packaging materials.
III. CONSUMER EXPOSURE DATA

No data are available on the amount of oiticica oil, if any, which is used in food packaging or which might involve food contact.

IV. BIOLOGICAL STUDIES

The Select Committee is not aware of any biological studies pertaining directly to the absorption, distribution, metabolism, excretion, or toxicology of oiticica oil or of its major constituent, licanic acid. Animals are known to consume the shell of the oiticica nut but reject the kernel, presumably because of its disagreeable taste and odor (François, 1952).
V. OPINION

No information could be found concerning the health aspects of ingesting oiticica oil or its major component, licanic acid. There is no evidence that the oil is now being used in packaging materials or other food contact surfaces. If it should be so used, the amounts which could migrate to food, while unknown, are presumed to be small. Nevertheless, the Select Committee concludes that:

In view of the complete lack of relevant biological studies, there are insufficient data upon which to base an evaluation of the health aspects of oiticica oil should it be used as a component of food packaging materials or in other food contact surfaces.
VI. REFERENCES CITED


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Report submitted by:

April 30, 1981  

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