EVALUATION OF THE HEALTH ASPECTS OF JAPAN WAX
AS A SUBSTANCE MIGRATING TO FOOD FROM COTTON OR
COTTON FABRICS USED IN DRY FOOD PACKAGING

1975

Prepared for

Bureau of Foods
Food and Drug Administration
Department of Health, Education, and Welfare
Washington, D.C.

Contract No. FDA 223-75-2004
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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 is one of a series concerning the health aspects of using the Generally Recognized as Safe (GRAS) or prior sanctioned food substances as food ingredients, being made by the Federation of American Societies for Experimental Biology (FASEB) under contract no. 223-75-2004 with the Food and Drug Administration (FDA), U.S. Department of Health, Education, and Welfare. The Federation recognizes that the safety of GRAS substances is of national significance, and that its resources are particularly suited to marshalling 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 Hearing Clerk, 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.

C. Jelleff Carr, Ph.D., Director
Life Sciences Research Office
FASEB
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I. INTRODUCTION

This report concerns the health aspects of using Japan wax as an ingredient of food packaging materials. It has been based partly on the information contained in a scientific literature review (monograph) furnished by FDA (1), which summarizes the world's scientific literature from 1920 through 1973. * To assure 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; recent literature searches by the Toxicology Information Response Center, Oak Ridge, Tennessee; 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, announcement was made in the Federal Register of February 13, 1976 (41 FR 6787 and 6788) 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 Japan wax as an ingredient of food packaging materials. The Select Committee received one request for such a hearing on Japan wax but this request was withdrawn.

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 Code of Federal Regulations 21 CFR 121.1, revised April 1, 1975, 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. This section of the Code also indicates 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 121.3) that it is impossible to provide assurance that any substance is absolutely safe for human consumption.

The Select Committee on GRAS Substances of LSRO is making its evaluations of these substances in full recognition of the foregoing provisions. In reaching its conclusions on safety, the Select Committee, in accordance with FDA's guidelines, is relying primarily on the absence of substantive evidence of, or reasonable grounds to suspect, a significant risk to the

*The document (PB-223 854/1) is available from the National Technical Information Service, U.S. Department of Commerce, P.O. Box 1553, Springfield, Virginia 22161.
public health. While the Select Committee realizes that a conclusion based on such reasoned judgment is expected even in instances where the available information is qualitatively or quantitatively limited, it recognizes that there can be instances where, in the judgment of the Select Committee, there are insufficient data upon which to base a conclusion. The Select Committee, aware that biological testing is dynamic, bases its conclusions on information now available; it cannot anticipate the results of experiments not yet conducted or those of tests that may be reconducted, using new technologies. These conclusions will need to be reviewed as new or better information becomes available.

In this context, the LSRO Select Committee on GRAS Substances has reviewed the available information on Japan wax 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

Japan wax is a tallow obtained from the fruits of the oriental sumac, *Rhus succedanea* (Japan, Formosa, and Indo-China), *R. vernicifera* (Japan) and *R. trichocarpa* (China, Indo-China, India, and Japan). Japan wax is prepared mostly from the mesocarp by hot pressing the immature fruit. Depending upon the method of preparation, the commercial tallow may contain more or less of the kernel fat which alters its melting range. Japan wax may be bleached by exposing flakes to sunlight for some days or weeks (2, 3).

The approximate composition of Japan wax is given in Table I (2). The wax is unusual in that it contains glycerides of the C_{18}-C_{23} dibasic acids and also has a particularly high content of tripalmitin. The former are credited with giving Japan wax its characteristic properties of toughness and ability to be kneaded without crumbling.

Some of the physical characteristics of Japan wax are as follows: acid value, 6 to 20; saponification value, 206.5 to 237.5; iodine value, 4.5 to 17; unsaponifiable matter, 0.5 to 1.7 percent; specific gravity, 0.975 to 1.00; melting range, 45 to 53°C (2, 3). The substance is not listed in Food Chemicals Codex (4).

Uses of Japan wax include the manufacture of candles, wax matches, pomades, creams, polishes, textile finishes and sizing, and lubricant for cordage and leather dressing (2).
TABLE I

Approximate Composition of Japan Wax (2)

<table>
<thead>
<tr>
<th>Component</th>
<th>Percent</th>
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<tbody>
<tr>
<td>Glycerides of monobasic acids</td>
<td></td>
</tr>
<tr>
<td>Palmitin, 76-82%</td>
<td>90-91</td>
</tr>
<tr>
<td>Stearin, 4-6%</td>
<td></td>
</tr>
<tr>
<td>Arachidin and lignocerin, 2-3%</td>
<td></td>
</tr>
<tr>
<td>Olein (4-8%) and linolein (trace)</td>
<td></td>
</tr>
<tr>
<td>Glycerides of dibasic acids</td>
<td>3-6.5</td>
</tr>
<tr>
<td>C₁₉ to C₂₃ dicarboxylic acids</td>
<td></td>
</tr>
<tr>
<td>Free fatty acids</td>
<td>3.7-5.6</td>
</tr>
<tr>
<td>Saturated: C₉, C₁₈</td>
<td></td>
</tr>
<tr>
<td>Unsaturated: oleic and linoleic</td>
<td></td>
</tr>
<tr>
<td>Free alcohols</td>
<td>1.2-1.6</td>
</tr>
<tr>
<td>Monohydrhic aliphatics: C₂₀, C₂₆, C₃₀</td>
<td></td>
</tr>
<tr>
<td>Glycerol</td>
<td></td>
</tr>
<tr>
<td>Sterols: β-sitosterol, 0.7%</td>
<td></td>
</tr>
</tbody>
</table>

Japan wax is generally recognized as safe (GRAS) in the Code of Federal Regulations (5) as a substance migrating to food from cotton and cotton fabrics used in dry food packaging [CFR 121.101(i)]. As a regulated substance, Japan wax is permitted as a component of paper and paperboard intended for use in producing, manufacturing, treating, packaging, transporting, or holding aqueous or fatty foods [CFR 121.2526].

III. CONSUMER EXPOSURE DATA

No direct food uses of Japan wax have come to the attention of the Select Committee and the substance is not included in the report of a survey conducted by a National Research Council subcommittee (6) on the use by industry of food chemicals generally recognized as safe (GRAS). In recent years total annual imports have varied from 321,000 pounds (146,000 kg) in 1968 to 97,000 pounds (44,000 kg) in 1972 (7). From the largest annual import it may be calculated, assuming a population of 205 million, that about 2 mg is available per person per day. Most domestic consumption is almost certainly in non-food uses; thus the quantity used in cotton packaging materials for dry foods is likely to be a fraction of a milligram per person per day. No
data are available on the extent of migration of Japan wax from packaging material to food but one may assume that migration will be a small percentage of that present. It is probable, therefore, that exposure from this source is no more than a small fraction of a milligram per person per day.

IV. BIOLOGICAL STUDIES

Only one early study, involving the feeding of Japan wax to four rats, was available to the Select Committee. Four rachitic rats were fed Japan wax at a 2 percent level (about 2 g per kg of body weight) in their rations. Two animals gained weight over 8 to 16 days and one lost weight; the fourth lost weight and died after 22 days. No antirachitic effect was produced by feeding the wax (8).

Digestibility of tripalmitin (M. P. 66.5°C), the major constituent of Japan wax, was determined in adult female rats fed rations containing 15 percent of the triglyceride (about 10 g per kg of body weight). Coefficient of digestibility was 12.8 for rations containing 7 percent of the Osborne-Mendel salt mixture (6.1 mg calcium and 0.9 mg magnesium per gram ration) and 27.9 for rations in which the calcium and magnesium salts had been omitted from the salt mixture. However, digestibility of tripalmitin as a component of a diet containing unsaturated fats may be higher since increasing the fluidity of saturated fats by the addition of unsaturated fat markedly increases the digestibility (9).

In vitro mutagenic evaluation of Japan wax using Saccharomyces cerevisiae, strain D4 and Salmonella typhimurium, strains TA-1536, TA-1537, and TA-1538, with and without metabolic activation with liver, lung, kidney or testis homogenates from mice, rats, or monkeys, revealed that it exhibits no genetic activity (10). Dimethylsulfoxide was used as the solvent; dose levels of the wax were 0.015 to 0.060 percent in the Salmonella tests and 0.125 to 0.500 percent in the tests with Saccharomyces.

No reports were available to the Select Committee on the acute toxicity, long-term feeding, carcinogenicity or teratogenicity of Japan wax.
Japan wax is a substance of plant origin which is generally recognized as safe (GRAS) as a substance migrating to food from cotton and cotton fabrics used in dry food packaging. However, the Select Committee has found no information on the acute toxicity of this substance, or reports of long-term feeding studies, or studies of its carcinogenicity or teratogenicity.

In view of the almost complete lack of biological studies, the Select Committee has insufficient data upon which to evaluate the safety of Japan wax as a substance migrating to food from cotton and cotton fabrics used in dry food packaging.
VI. REFERENCES CITED


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July 21, 1976
Date

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