EVALUATION OF THE HEALTH ASPECTS OF CARNAUBA WAX
AS A FOOD INGREDIENT

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

This report concerns the health aspects of using carnauba wax as a food ingredient. 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 10, 1976 (41 FR 5862 and 5863) 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 carnauba wax as a food ingredient. The Select Committee received three requests for such a hearing but these requests were 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

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*The document (PB-223 855/8) 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 recomducted, 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 carnauba 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

Carnauba wax is obtained from the leaves and buds of the Brazilian wax palm, Copernicia cerifera Martius. The wax is hard, brittle, sparingly soluble in cold organic solvents and insoluble in water (2, 3). It is marketed in five grades designated No. 1 and No. 2 (yellows), No. 3 (light fatty grey), No. 4 (fatty grey) and No. 5 (chalky). The latter two grades represent the bulk of the trade volume (4). The approximate chemical composition given in Table I apparently is representative of the commercial grades (4, 5). Vandenberg and Wilder found that the composition of No. 4 carnauba wax was essentially the same as that of No. 1, with the exception that for No. 4, the cinnamic esters were highly polymerized and no uncombined triterpenediol could be isolated (5). Variations reported in proportions of the major classes of constituents, as well as in proportions of components within the classes, may reflect differences in analytical methodology as well as sample composition (6-11).

Specifications for carnauba wax as given in the Food Chemicals Codex (3) are:

- Acid value: Between 2 and 10
- Ester value: Between 75 and 85
- Melting range: Between 82° and 86°C
- Unsaponifiable matter: Between 50 and 55 percent
- Limit of impurities:
  - Arsenic (as As): ‡ 3 ppm
  - Heavy metals (as Pb): ‡ 40 ppm
  - Lead: ‡ 10 ppm
<table>
<thead>
<tr>
<th>Component</th>
<th>Amount percent</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Free acids</td>
<td>5.5</td>
<td>Primarily C_{24}, C_{26}, C_{28} normal saturated monocarboxylic fatty acids</td>
</tr>
<tr>
<td>aliphatic acids, 4%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>aromatic acids, 1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>w-hydroxy acids, 0.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Free alcohols</td>
<td>11</td>
<td>Primarily C_{30}, C_{32}, C_{34} normal saturated monohydric primary fatty alcohols, C_{32} dominant</td>
</tr>
<tr>
<td>Hydrocarbons</td>
<td>1</td>
<td>Primarily C_{27}, C_{29}, C_{31} normal saturated hydrocarbons</td>
</tr>
<tr>
<td>Esters</td>
<td>82</td>
<td>45.3% normal saturated monofunctional acids, primarily C_{24}, C_{26}, C_{28} with 54.7% normal saturated monofunctional primary alcohols, primarily C_{30}, C_{32}, C_{34}, with C_{32} dominant</td>
</tr>
<tr>
<td>aliphatic, 40%</td>
<td></td>
<td>47.0% normal saturated monocarboxylic acids. 90% w-hydroxy acids, primarily C_{22}, C_{24}, C_{26}, C_{28}, and 10% normal saturated monocarboxyl acids, primarily C_{24}, C_{26}, C_{28} with 53.0% normal saturated primary alcohols. 90% monohydric alcohols, primarily C_{24}, C_{26}, C_{28}, C_{30}, C_{32}, and 10% α,ω-dihydric alcohols, (glycols) C_{24}, C_{26}, C_{28}, C_{30}, C_{32}, C_{34}</td>
</tr>
<tr>
<td>w-hydroxy, 13.2%</td>
<td></td>
<td>23.0% hydroxycinnamic acid, 5.8% p-methoxycinnamic acid, in each case esterified with α,ω-glycols as described above.</td>
</tr>
<tr>
<td>Cinnamic aliphatic diesters, 28.8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>0.5</td>
<td>Triterpenediol, plant pigments, etc.</td>
</tr>
</tbody>
</table>
The principal commercial source of carnauba wax is Brazil, and in 1970 slightly over 11 million pounds (4.9 million kg) were imported (12). Major use is in non-food applications as a component of polishes and carbon paper (4); a smaller quantity is used in food products principally in coatings for fresh fruit and soft candies (5,13). Data from a survey conducted by a National Research Council (NRC) subcommittee accounted for 117,346 pounds (52,300 kg) of carnauba wax in food applications in 1970, an amount the NRC subcommittee suggested might represent about 60 percent of the total amount used in foods (13). Thus, the total quantity used in foods in that year is estimated to have been 196,000 pounds (87,500 kg). In this survey, the first use of carnauba wax in food in the United States was reported to be in 1900.

Carnauba wax is generally recognized as safe (GRAS) in the Code of Federal Regulations as a miscellaneous and/or general purpose food additive (14).

III. CONSUMER EXPOSURE DATA

The NRC survey (13) also provided information on the level of addition of carnauba wax to foods in several food categories, as given in Table II. Based on information supplied by those manufacturers who reported adding the substance to at least one food in a category, a weighted mean was calculated for the usual and maximal addition of the substance to a food category. Only the weighted mean usual level of addition is reported in Table II.

The NRC subcommittee also computed possible average daily human intake of carnauba wax (Table III) from the four food categories on the basis of addition levels given in Table II, data from the Market Research Corporation of America on the frequency of eating foods in these food categories by individuals in four age groups, and U.S. Department of Agriculture data on mean portion size. The subcommittee pointed out that its calculations of intakes are overstated in most cases, often by considerable margins.*

*An explanation for such overstatements is detailed in Section XI, "Significance and Use of Data in Safety Evaluations," of the NRC subcommittee's report (13). The Select Committee finds this explanation reasonable and concurs in the first recommendation in Section XII of the same report, that "In order to conduct a more accurate survey of the intake of substances used in food processing, food consumption data collected specifically for this purpose are needed."
### TABLE II

**Level of Addition of Carnauba Wax to Foods by Food Category (13)**

<table>
<thead>
<tr>
<th>Food category</th>
<th>Weighted mean percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baked goods, baking mixes</td>
<td>0.00045</td>
</tr>
<tr>
<td>Processed fruits, juices, and drinks</td>
<td>0.00150</td>
</tr>
<tr>
<td>Soft candy</td>
<td>0.04223</td>
</tr>
<tr>
<td>Sugar, confections</td>
<td>0.01429</td>
</tr>
<tr>
<td>Chewing gum</td>
<td>***b</td>
</tr>
</tbody>
</table>

*Level of addition of carnauba wax is the weighted mean of the levels reported by manufacturers as their usual addition to one or more products in a food category. For discussion of weighted mean see Section X and Exhibit 50 of reference 13. Asterisks mean that (a) the substance is used in a processing phase of the foods indicated but residual levels in the final food products are negligible or unknown, or (b) the substance is used in the foods indicated but usage levels were not furnished by industry, or (c) the substance is in the foods indicated but the levels were considered to be reported incorrectly (see explanatory notes in Exhibit 50 of reference 13).
TABLE III

Possible Average Daily Intake of Carnauba Wax by Age Group (13)

<table>
<thead>
<tr>
<th>Age group</th>
<th>Intake</th>
<th>mg/kg&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-5 months</td>
<td>0.2</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>6-11 months</td>
<td>1.8</td>
<td>0.2</td>
</tr>
<tr>
<td>12-23 months</td>
<td>3.3</td>
<td>0.3</td>
</tr>
<tr>
<td>2-65+ years</td>
<td>4.9</td>
<td>&lt;0.1</td>
</tr>
</tbody>
</table>

<sup>a</sup>Calculated intake, mg/kg body weight was based on an average weight of 60 kg for an adult (15) and the following estimated weights of infants by age groups: 0-5 mo, 5 kg; 6-11 mo, 8 kg; and 12-23 mo, 11 kg (16).

That intakes are overstated in the case of carnauba wax is suggested by comparing a national consumption of 805,000 pounds (360,000 kg), calculated from the possible average adult intake in Table III, with total 1970 usage, 196,000 pounds (87,500 kg) estimated from NRC survey data (13) or 4.9 mg versus 1.2 mg per person per day.

Carnauba wax usage in processed fruit appears to be restricted to coatings of washed, fresh fruit. The principal fruit coated, which may be eaten unpeeled, is apples (17,18). If it is assumed that the level of addition given in Table II applies to all apples marketed fresh (19), then about 49,000 pounds (22,000 kg) of carnauba wax would be used for this purpose. If all treated apples were eaten unpeeled and no wax were removed in washing, this would account for a per capita daily intake of 0.3 mg as compared to the NRC estimate of 1.8 mg for processed fruits.

IV. BIOLOGICAL STUDIES

Mitchell (20) reported that carnauba wax is a skin-sensitizing agent and may serve as an allergen.
Carnauba wax (thin, yellow flakes of unspecified grade) did not produce responses indicative of a mutagenic chemical in nonactivation and activation assays for mutagenicity with Salmonella typhimurium, strains TA-1535, TA-1537, and TA-1538 and Saccharomyces cerevisiae, strain D4. Carnauba wax concentration was 0.01 percent in plate tests with S. typhimurium and 0.005 and 0.01 percent in suspension tests; concentrations in suspension tests with S. cerevisiae were 0.35 and 1.75 percent. Dimethyl sulfoxide was used to dissolve the carnauba wax (21).

The Select Committee found no reports on the absorption, metabolism, excretion, acute or chronic toxicity, teratogenic or carcinogenic properties of carnauba wax.

V. OPINION

Carnauba wax is a substance of plant origin that is used at a low level of addition in a limited number of food products. The per capita adult daily intake has been estimated to be about 1.2 mg. Despite its use in food since 1900, an extensive search of the literature has revealed no information on its absorption, metabolism or excretion by animals, acute or chronic toxicity, or its teratogenic or carcinogenic properties.

In view of the almost complete lack of biological studies, the Select Committee has insufficient data upon which to evaluate the safety of carnauba wax as a miscellaneous or general purpose food additive.
VI. REFERENCES CITED


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Date

George W. Irving, Jr., Chairman
Select Committee on GRAS Substances