EVALUATION OF THE HEALTH ASPECTS OF STEARYL ALCOHOL
AS A FOOD INGREDIENT

1980

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 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.

Kenneth D. Fisher, Ph.D., Director
Life Sciences Research Office
FASEB
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I. INTRODUCTION

This report concerns the health aspects of using stearyl alcohol as a food ingredient. It has been based partly on the information contained in a scientific literature review (monograph) furnished by FDA (Dufour and LeDoyen, 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, announcement was made in the Federal Register of April 25, 1980 (45 FR 27992-27995) that opportunity would be provided for any interested person to appear before the Select Committee at a public hearing to make an oral presentation of data, information and views on the health aspects of using stearyl alcohol 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 [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 (Office of the Federal Register, 1980). 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 [21 CFR 170.30] recognizes further that it is impossible to provide assurance that any substance is absolutely safe for human consumption (Office of the Federal Register, 1980).

The Select Committee on GRAS Substances of LSRO reviewed and evaluated the available information on stearyl alcohol 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. This report is intended for the use of FDA in determining the future status of this substance under the Federal Food, Drug, and Cosmetic Act. The Committee anticipates that its conclusions will be reviewed as new information becomes available.
II. BACKGROUND INFORMATION

Stearyl alcohol, \( \text{CH}_3(\text{CH}_2)_{16}\text{CH}_2\text{OH} \) (1-octadecanol, \( n \)-octadecyl alcohol) is a white, crystalline, and waxlike solid, with a faint fatty odor. At room temperature it is insoluble in water, but partly soluble in benzene, ethanol, acetone, and ether. It melts at 59.4-59.8°C and boils (at 15 torr) at 210.5°C (The Merck Index, 1976; Monick, 1968). It has been detected in apples and cranberries (van Straten, 1977), and occurs naturally as an ester in montan wax, cotton, oil of herring, the caudal glands of the goose, and in the sperm and blubber oil of the whale, porpoise, and dolphin (Monick, 1968). Trace amounts of free stearyl alcohol have been detected in a variety of mammalian tissues (Bandi and Mangold, 1971; Blank and Snyder, 1970; Gilbertson et al., 1975; Natarajan and Schmid, 1977; Takahashi and Schmid, 1970). However, it is most commonly found as a component of wax esters in specialized glands (Rock et al., 1978; Snyder and Blank, 1969) and in skin (Hougen, 1955; O'Neill and Gershbein, 1976a,b). Stearyl alcohol is also utilized in the synthesis of glyceryl ether lipids which are found in substantial amounts in numerous mammalian and nonmammalian tissues (Snyder, 1969).

The properties of blandness and white color make stearyl alcohol a desirable base for ointments, cosmetics, and suppositories. It is also used as an antifoaming agent, a leather softener, and an ingredient in ink and polishing preparations. It serves as an intermediate in the preparation of lubricating oil additives, textile finishing agents, and insecticides. Various derivatives are biodegradable detergents and textile softeners (The Merck Index, 1976; Monick, 1968).

In foods, stearyl alcohol has been accorded unpublished GRAS status as a component of enrichment tablets (Cassidy, 1960a) and as a coating agent (together with beeswax) for certain vitamin preparations (Cassidy, 1960b). It is also permitted in foods as a regulated substance and as a component of various food contact articles (Table 1) (Office of the Federal Register, 1980). A patent has been granted for the use of stearyl alcohol and other fatty alcohols as sprays on fresh unfrozen meats to reduce shrinkage and to prolong the normal appearance of meats (Anderson, 1960). The Select Committee is not aware that this use has been approved by the FDA.

Food grade specifications have not been established. The United States Pharmacopeia (1975) specifies that preparations so designated must contain at least 90% stearyl alcohol, with the remaining 10% to consist chiefly of cetyl alcohol (\( \text{CH}_3(\text{CH}_2)_{14}\text{CH}_2\text{OH} \)). The melting range of the preparation should be between 55° and 60°C, its acid and iodine values should not exceed 2, and its hydroxyl value should be between 200 and 220.
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<td><strong>Regulated Uses</strong></td>
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<td>Used in food and in synthesis of food components</td>
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<td>Contains not less than 98% of total alcohols and not less than 94% of straight chain alcohols. Any non-alcoholic impurities are primarily paraffins. Contains not more than 0.1% by weight of total diols.</td>
</tr>
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<td>Component of adhesives</td>
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<td>Stearyl-cetyl alcohol mixture used contains approximately 65-80% stearyl alcohol and 20-35% cetyl alcohol</td>
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<td>Must meet specifications of 21 CFR 172.846 and contain no more than 0.8% total diols</td>
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III. CONSUMER EXPOSURE DATA

The Select Committee has been unable to obtain information on the levels of stearyl alcohol used in processed foods. Information obtained from manufacturers of vitamin-iron tablets employed to enrich bread and buns indicated that stearyl alcohol is not now used for this purpose (Glover, 1979; Borowski, 1979). The Select Committee was also unable to obtain evidence that it is currently used in coating agents for vitamin preparations.

The regulated authorized uses of stearyl alcohol would appear to contribute little to foods. A major use appears to be in cosmetics, especially in skin lotions. Some may be used in lipsticks at levels of 1-2% of the final product (Egan, 1979). A survey of 222 lipstick users revealed an average ingestion of 22 mg with a maximum of 75 mg/day (Estrin, 1979). Thus, approximately 1 mg stearyl alcohol/day could be ingested from this source.
Absorption and excretion

Stearyl alcohol is absorbed slowly and incompletely from the gastrointestinal tract. Miyazaki (1955) reported that 19% of stearyl alcohol was absorbed by albino rats (strain not identified) from diets containing 5% of the compound (about 5 g/kg body weight/day). Yoshida et al. (1970) investigated the possible utility of various alcohols as energy sources for poultry. They reported that alcohols containing more than 14 carbon atoms were poorly utilized because of their low absorbability. The absorption of cetyl alcohol (16 carbons) was 26% and that of stearyl alcohol, although not determined, was suspected to be even lower. In a subsequent report from the same laboratory (Yoshida and Hoshii, 1971), the absorption of stearyl alcohol in chicks was stated to be zero. Macht (1933) found stearyl alcohol to have a laxative action in rats when given intragastrically as a 1% emulsion with finely divided charcoal. However, Calbert et al. (1951) reported that stearyl alcohol was well absorbed (89%) by adult rats when it constituted 1.8% of the diet (about 1.8 g/kg body weight/day). When the dietary stearyl alcohol was increased to 7.5% (about 7.5 g/kg body weight/day), only 55% was absorbed. The higher level of stearyl alcohol also reduced the absorption of dietary margarine. The authors attributed this effect to the increased melting point of the fat resulting from the stearyl alcohol addition.

Long-chain fatty alcohols have been found in the intestinal tract of various animals which had not received these compounds in their diets (Schoenheimer and Hilgetag, 1934). This suggests their formation either by microbial production in the intestinal tract or by endogenous production in the body and subsequent secretion into the intestinal lumen. Schoenheimer and Hilgetag (1934) isolated cetyl alcohol in sterile feces of infants (meconium) and in sterile experimental intestinal loops of dogs, ruling out bacterial production. They also identified both cetyl and stearyl alcohols in the feces of dogs with bile-duct fistulas, excluding bile as the source of the alcohols in the intestines. Thus, cetyl and stearyl alcohols are apparently produced in the body and secreted through the intestinal mucosa into the lumen.

The immediate source of the cetyl and stearyl alcohols in the intestinal tract appears to be their corresponding fatty acids. Stetten and Schoenheimer (1940) demonstrated the interconvertibility of fatty acids and alcohols by the rat. When deuterolabeled palmitic acid was fed to rats, it was converted to cetyl alcohol. This finding was confirmed by Bandi and Mangold (1971) who found cetyl and stearyl alcohols in the feces of Sprague-Dawley rats whose dietary lipids contained palmitic and stearic acids, respectively. Conversely, the acetates of labeled cetyl and stearyl alcohols were readily absorbed and rapidly converted
to palmitic and stearic acids (Stetten and Schoenheimer, 1940). The site(s) of the conversions was not investigated. Blomstrand and Rumpf (1954) concluded that the conversion of fatty alcohols to fatty acids occurred during their passage through the intestinal mucosal cells. They fed labeled cetyl alcohol to rats (strain not identified) with thoracic duct fistulas. Most of the activity (63–96%) appeared in the lymph, indicating good absorption. About 15% of the alcohol was unchanged during its passage through the mucosal cells whereas most was oxidized to palmitic acid and incorporated into triglycerides and phospholipids. Friedberg (1976) extended these studies by reexamining the transport forms of fatty alcohols in the blood following their absorption from the gastrointestinal tract. Labeled cetyl alcohol was administered by stomach tube to Sprague-Dawley rats and the radioactivity of the various lipid components in blood plasma determined at intervals up to 4 h after intubation. Friedberg confirmed the findings of Blomstrand and Rumpf (1954) that significant amounts of the fatty alcohols (3–23%) were absorbed unchanged. Most activity was present in the triglyceride fraction (22–43%), with lesser amounts in the diacylglycerol ether (6–25%) and the phospholipid (10–14%) fractions. Small amounts of the label had also been incorporated into the wax esters (4–13%) and into free fatty acids (1–9%).

**Metabolism**

Although fatty alcohols, including stearyl alcohol, are found in various mammalian tissues and neoplasms and are of central importance in the formation of waxes and alkyl glycerolipids, relatively little is known of the biosynthetic pathways. As pointed out earlier, Stetten and Schoenheimer (1940) demonstrated the interconversion of fatty acids and alcohols in the intestinal tracts of rats. The first direct evidence of the conversion of fatty alcohols to fatty acids by cell-free extracts was obtained by Kolattukudy (1970) with preparations from *Euglena gracilis*. Since this demonstration, enzymatic synthesis of fatty alcohols have been accomplished with cell-free preparations of mouse preputial gland tumors (Snyder and Malone, 1970), young broccoli plants (Kolattukudy, 1971), developing rat brain (Natarajan and Sastry, 1976), and rabbit harderian gland (Rock et al., 1978). The fatty acid is believed first to be activated by coenzyme A and the resulting fatty acyl CoA is converted enzymatically to the fatty aldehyde and then to the fatty alcohol. Partially purified enzymes have been isolated, which catalyze the conversion of fatty acid to fatty aldehyde (Johnson and Gilbertson, 1972), and fatty aldehyde to fatty alcohol (Kessler and Ferrell, 1974).

Fatty alcohols serve as precursors of biologically important waxes and lipid ethers. Waxes are well-known components of skin lipids (Nicolaudes, 1974) and of various fish oils (Spener and Mangold, 1971). Friedberg and Greene (1967) reported the presence of an enzyme system in both mammalian and fish livers which catalyzed the conversion of cetyl alcohol to wax. Although
cetyl alcohol appeared to be the major fatty alcohol in these liver preparations, small amounts of stearyl and oleyl alcohols were also detected.

A vast literature has accumulated on the distribution, metabolism, and function of lipids containing ether bonds (Snyder, 1969; 1972). These ether lipids are widespread throughout the animal kingdom and have been found in bacteria, protozoans, elasmobranch fish, echinoderms, gastropods, and mammals, including man (Snyder, 1969). They may exist as O-alkyl ethers, which are stable, or as O-alk-1-eny1 ethers which are acid labile and which give rise to aldehydes on hydrolysis. Both ether forms occur as constituents of phosphatides and of neutral lipids. The O-alk-1-eny1 ethers of phosphatides are known as plasmalogens and those of the neutral lipids as neutral plasmalogens. Ellingboe and Karnovsky (1967) reported that both stearyl alcohol and stearyl aldehyde could serve as precursors for the alkyl and the alk-1-eny1 chain of the glycerolipids in the digestive tract of the starfish. Stearyl alcohol was incorporated into the alkyl ethers more efficiently than was stearyl aldehyde, but the aldehyde served as a better precursor than the alcohol in the biosynthesis of alkenyl ethers.

The first step in the biosynthesis of lipid ethers appears to be the conversion of the fatty alcohol to alkyl dihydroacetone phosphate (DHAP) by alkyl DHAP synthase. Natarajan and Schmid (1978) incubated labeled fatty alcohols with brain microsomal preparations from 19-day-old rat (strain not identified) and reported the formation of alkyl DHAP. Of all the alcohols tested, oleyl and cetyl alcohols served as the most efficient alkyl donors, with stearyl alcohol somewhat less effective. Rat brain microsomes were also efficient in converting fatty acids (12-22 carbons) to the corresponding alcohol. The conversion of palmitic acid to cetyl alcohol was the most efficient of these reductions with the formation of stearyl alcohol from stearic acid the next most efficient.

The common occurrence of glyceryl ethers in significant amounts in a variety of animal tissues has stimulated speculation on their biological functions. Among the suggested functions and effects are growth stimulation, neurogenic activity, inhibition of hemolysis, bacteriostasis, radioprotection, and wound healing (Snyder, 1969). No specific role has yet been identified but Friedberg and Halpert (1978) speculate that the abundance of ether lipids in certain tissues such as the heart and central nervous system points to some critical function. The alk-1-eny1 lipids predominate in mammalian tissues with the notable exception of neoplasms (Friedberg and Halpert, 1978) where the O-alkyl glyceryl ethers have been found in abnormal amounts.

Most studies of biologically significant ethers have concentrated on the ethers of glycerol, although similar ethers of diols have also been detected in many living organisms (Bergelson, 1973; Bergelson et al., 1966). Bergelson (1973) in his review of
diol lipids reported a number of diol ethers which have been detected in plants, fish, and mammals. Their biosynthetic pathways appear to be similar to those of the glycerolipids and to be enhanced during periods of rapid growth. Their biological significance is unknown.

**Acute toxicity**

Although specific data are limited, stearyl alcohol is generally reported to have a low oral toxicity (Gosselin et al., 1976; Sax, 1975). Egan and Portwood (1974) stated that the LD<sub>50</sub> of both natural and synthetic stearyl alcohol in male and female Holtzman rats was greater than 8.0 g/kg body weight. The Proctor and Gamble Company [1979] (the major producers of stearyl alcohol) claims that 20 g/kg body weight have been given to rats without causing death of any animal. The only other acute toxicity study known to the Select Committee is an aquatic toxicity rating of 0, reported by the National Institute of Occupational Safety and Health (NIOSH) (1977). This rating indicates that the concentration of stearyl alcohol required to kill 50% of exposed aquatic organisms within 96 h was greater than 1000 mg/liter. NIOSH considers this level of toxicity to represent an "insignificant hazard."

**Short-term studies**

Calbert et al. (1951) fed stearyl alcohol at levels of approximately 1.8 and 7.5 g/kg body weight/day to two groups of female rats weighing about 200 g (strain not identified). Ten rats received the lesser level of stearyl alcohol and nine, the greater amount for 13 days. The former groups showed normal weight gains but those on the higher dosage lost weight during the test period. No other effects were reported.

Miyazaki (1955) compared the nutritive value of a number of saturated alcohols fed to young rats (60-80 g) for 30 days. The alcohols constituted 10% of the basal diet. Three rats (sex and strain not stated) consumed approximately 10 g/kg body weight of stearyl alcohol/day. All survived the test period with normal weight gains. No signs of toxicity were reported.

Yoshida and Hoshii (1971) maintained four 1-day-old Leghorn chicks for 3 weeks on a diet containing 10% stearyl alcohol (about 8 g/kg body weight/day). All survived the test period with no reported toxic effects.

**Long-term studies**

No long-term studies have come to the attention of the Select Committee.
Carcinogenicity

Brooks et al. (1957) tested a number of compounds, including stearyl alcohol, for possible carcinogenicity. They employed a screening test based on the rapid destruction of the sebaceous glands and the decrease of delta-7-cholestenol in the epidermis of mice when carcinogenic agents were applied. They applied 30 mg stearyl alcohol to the shaved areas of the backs of two male albino Rockland mice on the first, third, and fifth day of the experiment. Skin specimens were removed on the sixth day and examined histologically and chemically. They found that stearyl alcohol produced hyperplasia as indicated by increased epidermal weight and cholesterol per unit area. However, it did not damage the sebaceous glands nor affect the epidermal delta-7-cholestenol. No carcinogenic changes were noted.

Brun et al. (1956) also reported that an ointment containing stearyl alcohol, sodium cetyl sulfate, and water (25:1:200) lightly massaged on the shorn flanks of guinea pigs eight times during a 10-day period, induced epidermal thickening of about 50%.

Sicé (1966) studied the tumor-promoting activity of a number of normal alkanes and alkanols with chain lengths of 6–20 carbon atoms. An initiating dose of 7,12-dimethylbenz(a)anthracene was applied to the shaved skin of female Swiss mice. Beginning 1 week later, one drop of a cyclohexane solution containing about 4 mg stearyl alcohol was applied over the area of the initiated skin three times weekly for 60 weeks. Twenty-three of 30 mice survived the test period. In one mouse a tumor appeared after 30 weeks' treatment with stearyl alcohol. Compared with some of the other substances tested (especially decane and decanol), stearyl alcohol proved to be a very weak tumor-promoting agent.

Boyland et al. (1964) evaluated various "inert" substances for possible use as media for bladder implants to test suspected carcinogens. Stearyl alcohol was introduced in pellet form into the bladders of 50 stock mice, bred at the Chester Beatty Research Institute. They were observed for 30 weeks for tumor induction. Seven adenomas or papillomas and six carcinomas were induced in the animals with stearyl alcohol implants, for a 26% tumor incidence, compared with 2–32% with other "inert" substances tested (cholesterol, paraffin wax, naphthalene, glass, stearic acid, magnesium stearate, cetyl alcohol).

The Select Committee is not aware of any carcinogenicity studies with oral administration of stearyl alcohol.

Mutagenicity, teratogenicity

No studies on possible mutagenic or teratogenic activity of stearyl alcohol have come to the attention of the Select Committee.
Special studies

The use of stearyl alcohol in cosmetics and ointments has prompted its testing for local irritant or allergic reaction. Hjorth and Trolle-Lassen (1963) reported it to be almost free of irritant reaction. Using 30% stearyl alcohol in liquid paraffin, they obtained only four positive patch tests among 1664 consecutive patients with a history of eczema. Shore and Shelley (1974) described a case of contact dermatitis with 30% commercial stearyl alcohol. No visible reaction occurred, however, when the patient was tested with 30% "high-grade" stearyl alcohol. Gaul (1969) reported that a preparation of 3% stearyl alcohol in petrolatum produced an urticarial-type response at the point of contact. The purity of the stearyl alcohol was not indicated.

Stearyl alcohol was ineffective in retarding the tuberculous process in guinea pigs (Nègre et al., 1945) or Ehrlich carcinoma in mice (Ando et al., 1972).

Stearyl alcohol administered subcutaneously with the hormone increased the activity in rats (strain not identified) of both estrone (Miescher et al., 1938) and of testosterone (Miescher et al., 1936). It was the most effective of all alcohols tested.
V. OPINION

Stearyl alcohol is a solid, long-chain, fatty alcohol found naturally in plants and animals. It is a normal intermediate in fat metabolism and is readily converted to stearic acid, a common constituent of animal tissues. It serves as a precursor of a number of biologically important ether lipids. It is poorly absorbed from the gastrointestinal tract. Acute and short-term studies indicate a very low order of toxicity, but long-term toxicity studies have not been reported.

Stearyl alcohol is used chiefly as a lubricant, as a component of various coatings contacting food, and as a component of cosmetics. It does not appear to be used currently in its GRAS application as a component of vitamin enrichment tablets or as a coating agent (together with beeswax) for vitamin preparations.

Food-grade specifications for stearyl alcohol are not available. They should be established to ensure uniformity of composition and the effective control of possible contaminants.

Based on these considerations, the Select Committee concludes that:

There is no evidence in the available information on stearyl alcohol that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public should it be used as a component of vitamin and mineral enrichment tablets for bakery products or as a coating agent (together with beeswax) for vitamin preparations.
VI. REFERENCES


Stetten, D., Jr.; Schoenheimer, R. 1940. The biological relations of the higher aliphatic alcohols to fatty acids. J. Biol. Chem. 133:347-357.


VII. SCIENTISTS CONTRIBUTING TO THIS REPORT

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Report submitted by:

September 3, 1980

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