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ADM

James R. Randall Research Center

RECD JUL 12 2005

July 7, 2005

Dr. Robert L. Martin
DBGNR/OFAS/CFSAN/FDA HFS-255
5100 Paint Branch Parkway
College Park, MD 20740-3836

Re: GRAS Notification for Expanded Use of Plant Sterol and Sterol Esters

Dear Dr. Martin:

Archer Daniels Midland Company (ADM), by this letter and enclosed document, is providing the Food and Drug Administration ("FDA") notice in accordance with the FDA proposed regulation at 62 Fed. Reg. 18938, 18960 (April 17, 1997), that it has determined, based on a review of the data referenced in the enclosed document, that the substances, plant sterol and sterol esters, are generally recognized as safe ("GRAS") for use in food. These substances are the subject of previous GRAS notifications, as listed in the document.

The document contains a listing of 19 GRAS use categories for sterol and sterol esters incorporation into foods, and the GRAS use for these extended categories is fully supported by the safety studies and intake exposure calculations provided therein. This GRAS expansion determination is fully supported by a panel of experts, and their written concurrence is provided.

This GRAS notification is based on published, generally available and accepted scientific data, information, methods and principles, as well as experience based on common use in foods. ADM has determined that the use of plant sterol and sterol esters for use in certain foods is GRAS, and therefore, it is exempt from the premarket approval requirements of the Food, Drug and Cosmetic Act.

Very truly yours,

(b)

Mark W. Empie, Ph.D.
Vice President,
Regulatory and Scientific Affairs

MWE/jm

000001.001

GRAS EXEMPTION CLAIM FOR PLANT STEROLS AND PLANT STEROL ESTERS IN EXPANDED FOOD CATEGORIES

Proposed by:
Archer Daniels Midland Company
4666 Faries Parkway
Decatur, IL 62526

Revised
July 7, 2005

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I GRAS EXEMPTION CLAIM FOR PLANT STEROLS AND PLANT STEROL ESTERS IN EXPANDED FOOD CATEGORIES

A) Claim of Exemption from the Requirements for Pre-Market Approval.

1) Background

The safe use and health benefits of plant sterols and plant sterol esters has been well documented (1). Historically, sterols were first introduced in the U.S. and Canadian markets in the 1950's as a cholesterol lowering drug under the trade name of Cytellin (Eli Lilly). It stayed in the market for 29 years and it was discontinued due to the development of statin drugs. Therapeutic levels of Cytellin ranged from 9-30g/day and repeated clinical investigations reported no contraindications or side effects (2-4). More recently, the introduction in the market of functional foods containing phytosterols has contributed to the human exposure of sterols beyond levels naturally occurring in the diet. However, the safety of this increased dietary consumption has been thoroughly evaluated by scientists and health authorities in various countries, primarily in Europe and in the United States. As a result, since 1999 a series of market authorizations for the use of plant sterol and plant sterol esters have been granted to several companies in Europe and the United States for their use in a broad range of food categories. In the U.S., the FDA has been notified by various food companies about the regulatory self-determined Generally Recognized As Safe (GRAS) status for the use of plant sterol and plant sterol esters in products such as vegetable oil spreads (Lipton/Unilever, FDA letter from A.M. Rulis to D. Dwyer,

4/30/99; Novartis Consumer Health, Inc. GRN 000039, 4/24/00); vegetable oil spreads, dressing for salads, bars and yogurt (Cargill Incorporated, GRN 000048, 11/27/00); vegetable oils (The Procter and Gamble Company, GRN 000053, 12/20/00); and of vegetable oil spreads, dressing for salads, health drinks, health bars and yogurt-type products (Archer Daniels Midland Company, GRN 000061, 4/18/2001). More recently, on February 4, 2003, Teriaka, Ltd. gained self-affirmed GRAS status of an even wider range of products than those listed in the above notifications, by including beverages, ice cream, cheese and cream cheese-like products, snack bars, mayonnaise and some types of bread (Teriaka, Ltd., GRN 000112, 2/4/03). Copies of the FDA response letters to these GRAS notices can be found as Appendix A.

2) Scope of this Petition

Pursuant to proposed regulation 21 CFR 170.36, and following established scientific procedures, ADM notified the FDA on October 27, 2000 of the GRAS self-affirmation of plant sterols and plant sterol esters derived from edible vegetable oils for use as ingredients in vegetable oil spreads, dressings for salad, health drinks, health bars and yogurt type products. The corresponding non-objection letter from FDA was received in April, 2001 (GRAS Notice No. GRN 000061, April 18/01; See Appendix A).

In addition to the above, currently ADM intends to produce plant sterols and plant sterol esters derived from tall oil extracted from pine trees ("wood sterols"). Although other companies have already notified FDA of the GRAS self-affirmed status of other wood sterols (see GRAS Notices No. GRN 000039 and GRN 000112; Appendix A), ADM, by this submission, intends to notify FDA of the GRAS self-affirmed status of its wood sterols. Furthermore, based on current market demands, ADM intends to expand the food use categories indicated in its original GRAS notification to provide an expanded range of sterol-enriched products to the consumer, whether derived from vegetable oils or tall oils.

3) Exemption Claim

Pursuant to the regulatory and scientific procedures established by proposed regulation 21 CFR 170.36, ADM has determined that its wood sterols (free and sterified) derived from tall oil are GRAS substances for the intended food applications and are therefore exempt from the requirement for pre-market approval (21 CFR 170.36 (c) (1)). ADM has also concluded that plant sterols and plant sterol esters derived from either vegetable oils or tall oil are GRAS substances exempt from the requirement for pre-market approval (21 CFR 170.36 (c)(1), when applied to the following food categories: margarines and vegetable oil spreads, dressings for salads, healthy beverages, health bars, milk type products (including soy milk, ice cream and cream substitutes), cheese and cream, baked foods, adult ready to eat breakfast cereals, fruit/vegetable juices,

mayonnaise, pasta and noodles, sauces, salty snacks, processed soups, puddings, yogurt, adult confections, vegetarian meat analogs and edible vegetable oils, including diacylglycerol oil as a replacement.

The basis for this GRAS affirmation is described in the following sections.

B) Name and Address of Notifier

Archer Daniels Midland Company (ADM)

4666 East Faries Parkway

Decatur, IL 62526

Contact:

Luis A. Mejia, Ph.D.

Director of Regulatory & Scientific Affairs

1001 N. Brush College Rd.

Decatur, IL 62521

Tel. 217-451-2201

email: mejia@admworld.com

C) Name of GRAS Substance

The ingredients determined by ADM as GRAS are plant sterols and plant sterol esters derived from either vegetable oils or tall oils to be used in the products originally

notified to FDA on October 27, 2000 (GRAS Notice No. GRN 000061, April 18, 2001) and an expanded range of food categories, i.e., margarines and vegetable oil spreads, dressings for salads, healthy beverages, health bars, milk type products (including soy milk, ice cream and cream substitutes), cheese and cream, baked foods, adult ready to eat breakfast cereals, fruit/vegetable juices, mayonnaise, pasta and noodles, sauces, salty snacks, processed soups, puddings, yogurt, adult confections, vegetarian meat analogs and edible vegetable oils, including diacylglycerol oil as a replacement.

In terms of the plant sterols and sterol esters from vegetable oils, neither the product specifications nor the manufacturing process have changed from the original notification, as described in the GRN 000061. For those plant sterols and sterol esters from tall oils (i.e., "wood sterols"), the manufacturing information is provided below as part of this notification.

This notification also provides information regarding the use of a known emulsifier, Sucrose Fatty Acid Esters (SFAE) because certain food applications will require emulsification. In those instances, SFAEs will be added to the sterol-enriched food. FDA has already been notified of SFAE as a GRAS substance for specific food applications (GRAS Notice No. GRN 000129 to Mitsubishi Chemical Corporation, Nov. 7, 2003). It is also an approved food additive for use as emulsifier, stabilizer and texturizer in multiple food categories (21 CFR 172.859).

D) Intended use of Plant Sterols and Plant Sterol Esters

Plant sterols and plant sterol esters, derived from either vegetable oils or tall oil (wood sterols) will be incorporated into the following food categories up to a level of 0.4 g of free sterol equivalent per serving; with exception of fruit/vegetable juices in which the level of addition will be up to 1 g/serving, and edible vegetable oils, including diacylglycerol oil as a replacement, up to 4%. These phytosterol-enriched products will be available to adults, teenagers, and children older than 3 years, and these age groups have been used for consumption calculations.

1 - Margarine and vegetable oil spreads*
2 - Dressing for salads*
3 - Healthy beverages*
4 - Healthy bars*
5 - Milk type products* (includes soy milk, ice cream and cream substitutes)
6 - Cheese and cream*
7 - Selected baked foods*
8 - Adult RTE Breakfast cereals
9 - Fruit/vegetable juices
10 - Mayonnaise*
11 - Pasta and noodles
12 - Sauces
13 - Salty snacks
14 - Processed soups
15 - Puddings
16 - Yogurt*
17 - Adult confections
18 - Vegetarian meat analogs
19 - Edible vegetable oil* (includes diacylglycerol oil)

* Categories previously notified to FDA

As noted by the asterisks, the above list includes the food categories already authorized by the Agency to Lipton/Unilever (FDA letter from A.M. Rulis to D. Dwyer on 4/30/99), ADM (GRAS Notice No. 000061), Teriaka Ltd. (GRAS Notice No. 000112), Cargill (GRAS Notice No. 000048), Novartis Consumer Health (GRAS Notice No. 000039) and Procter & Gamble (GRAS Notice No. GRN 000053). The specific foods are identified in the attached appendices according to food codes listed in the U.S. Department of Agriculture (USDA) 1994-1996, 98 Continuing Survey of Food Intake by Individuals (CFSII 94-96-98), and these codes have been used to calculate the estimated daily intake (EDI) values for the consumption of plant sterols and plant sterol esters in the already indicated age groups of the U.S. population. The same procedure has been used to determine the consumption of sucrose fatty acid esters to be used as an emulsifier in certain food categories. (See Section IV-B, 2 below.)

E) Basis for GRAS Determination

1) Description of Safety Data

Pursuant to 21 CFR 170.30, ADM has determined that plant sterol and plant sterol esters, derived from either vegetable oils or tall oil, are GRAS substances for the intended applications based upon scientific procedures and by the supportive opinion of an external panel of experts (Appendix I). The four-member panel consisted of the same scientists in Lipton's GRAS panel which

originally reviewed the safety data submitted as part of Lipton's GRAS notification to the FDA on January 11, 1999 (Food Master File 625). ADM's GRAS petition for plant sterols on October 27, 2000 was also based on this information. In addition, the GRAS status of plant sterols and plant sterol esters in the intended applications is supported by more recent scientific information evaluated in Section IV (A) (1-3), and several years of use of these substances in various countries around the world as ingredients of a wide range of products such as margarine, fat spreads, health bars, health drinks, yogurt, mayonnaise, soy milk, milk type products and orange juice without reports of serious adverse effects. Plant sterol and plant sterol esters are considered today as one of the most studied food ingredients whose use in foods contributes effectively to the reduction of blood cholesterol.

2) Estimated Consumption

The previous ADM GRAS notification for plant sterol and plant sterol esters relied upon an estimated mean intake of 5.5 g/day and up to 10.6 g/day at the 90th percentile level and using 1 gm sterol per serving. This 10.6 g/day value was slightly higher than the 9.1 g/day ADI value established by the Lipton's GRAS panel for a reference adult individual (130 mg/kgBW/day x 70 kg). The present petition uses instead 0.4 g of sterol per serving. This new reference value is based on the phytosterol health claim authorized by FDA (65 FR 54685) in 2000, and the FDA enforcement discretion letter to Cargill Health and Food Technologies

issued on February 14, 2003. Using this new approach, the established sterol intake for adult individuals, including the already existing and newly proposed food categories, is 3.9 g/day; well below the 9.1 g/d ADI established by Lipton's GRAS panel.

3) General Recognition of Safety

As established in 21 CFR 170.30, a panel of experts qualified in the fields of medicine, nutrition, food safety and toxicology reviewed the data provided in this dossier. It is their authorative opinion that plant sterol and plant sterol esters derived either from vegetable oils or from tall oil are Generally Recognized as Safe for use as ingredients in the proposed food categories. This expert panel consisted of the same members as in the original Lipton GRAS panel, which was also the basis of the first ADM GRAS petition for the use of plant sterols (GRN 000061).

The members of the panel were:

Dr. Walter Glinsmann (Glinsmann, Inc., Arlington, VA 22207)

Dr. David Kritchevsky (Wistar Institute, Philadelphia, PA 19104)

Dr. Joseph Borzelleca (Toxicology and Pharmacology, Inc., Richmond, VA 23229)

Dr. Michael Pariza (Michael Pariza Consulting LLC, Madison, WI 53719)

As indicated in Appendix I, this panel concluded that ADM plant sterols and plant sterol esters, derived from either vegetable oils or from tall oil (wood sterols), meeting appropriate food grade specifications and manufactured in compliance with cGMP are GRAS by scientific procedures for use at levels and in the food categories indicated in this notification (see panel report, Appendix I).

4) The data and information that are the basis for ADM's GRAS determination are available for the FDA's review and copies will be sent to FDA upon request.

II IDENTITY AND SPECIFICATION OF PLANT STEROLS AND PLANT STEROL ESTERS

A) Sterols and Sterol Esters Derived from Vegetable Oils

Description, chemical composition, specifications and manufacturing process of plant sterols and plant sterol esters derived from edible vegetable oil are the same notified to the FDA in the original ADM submission to FDA on October 27, 2000 (GRAS notice 000061, Appendix A).

B) Sterols and Sterol Esters Derived from Tall Oil (Wood Sterols)

1) Identity and Product Description

The wood sterols product is an off-white powder consisting of a mixture of mainly β-sitosterol (CAS No. 83-46-5), β-sitostanol (CAS No. 19466-47-8), campesterol (CAS No. 474-62-4), campestanol (CAS No. 474-60-2) and stigmasterol (CAS No. 83-48-7). Melting range is 135-140°C. Corresponding chemical formulas of these compounds are presented as Appendix B. They are extracted from tall oil derived primarily from coniferous trees (Pinus pinaster and Pinus syvestris), as part of the wood pulp industry by-product. Their solubility in fat increases when the sterol is esterified with fatty acids and become sterol esters.

2) Product Specifications

The specifications of Wood Sterols are the following:

Total Free Sterols	99% minimum
β-Sitosterol	80% maximum
β-Sitostanol	15% maximum
Campesterol	40% maximum
Campestanol	5% maximum
Stigmasterol	30% maximum
Brassicasterol	6% maximum
Other Sterols	6% maximum
Heavy Metals	10 ppm maximum
Lead	2 ppm maximum

Free wood sterols can be converted to wood sterol esters by esterification with fatty acids as described in Section III-A.

Product to be exported to Europe will comply with European regulatory requirements specified in Commission Decision of 31/03/2004 regarding ADM's plant sterols/stanols.

C) Data on Representative Lots

The following table presents typical compositions of three different production lots (% weight dry basis).

	Lot Number		
	WSP 1004004	WSP 1104005	WSP 1104006
Total free sterols	100%	99.2%	99.0%
β-Sitosterol	78.9%	77.6%	77.8%
β-Sitostanol	10.2%	10.1%	10.0%
Campesterol	7.1%	7.0%	7.1%
Campestanol	1.1%	1.1%	1.0%
Stigmasterol	0.9%	0.9%	0.9%
Brassicasterol	0.0%	0.0%	0.0%
Other sterols	1.8%	2.5%	2.2%

Method of analysis: Gas Chromatography (ADM method E-0110)

Notice that all these lots meet the previously indicated specifications and that the sterol composition is very consistent from lot to lot.

III MANUFACTURING PROCESS FOR WOOD STEROLS AND WOOD STEROL ESTERS

A) Reaction Scheme and Manufacturing Flow Diagram

The manufacturing flow diagram for the production of wood sterols and wood sterol esters is presented as Appendix C. The starting material is tall oil derived from pine trees (Pinus pinaster and/or Pinus syvestris).

As indicated in the diagram, the feedstock, tall oil pitch, is saponified with caustic soda to form soaps from free fatty acids and other saponifiable impurities. Sterols and other unsaponifiable impurities are removed from the soaps by solvent extraction. The soaps are regenerated to free fatty acids by acidulation with sulfuric acid. Sterols are further concentrated by high vacuum, short-path distillation to produce a crude sterol concentrate. This concentrate is then dissolved in solvent, the resulting mixture is cooled to produce pure sterol crystals, and these crystals are isolated by vacuum filtration. The solvent extraction and crystallization steps remove impurities, including terpenoid compounds. The crystals are then dried to remove traces of solvent, and converted to powder or pastilles. Esterification to produce wood sterol esters is achieved by using standard industry esterification and transesterification methods.

B) Potential Contaminants

1) Heavy Metals

The results of heavy metal analysis of three different wood sterol production lots is presented in the following table. Heavy metals were not detected in any of the product tested.

Lot No.	Cu	As	Ag	Cd	Sn	Sb	Hg	Pb	Bi
WSP 1004004	ND	ND	ND	ND	ND	ND	ND	ND	ND
WSP 1104005	ND	ND	ND	ND	ND	ND	ND	ND	ND
WSP 1104006	ND	ND	ND	ND	ND	ND	ND	ND	ND

ND: Non-detectable (LOD: 1 ppm)

2) Microbiological Analysis

As shown in the following table, the microbiological results of wood sterols are representative of food grade material. The product is practically free of microbiological contaminants.

Lot No.	SCP/G	Sal.	Y & M	Colif/G	E. Coli	Therm/G	Meso/G	B. Cereus (presumptive)
WSP 1004004	< 10	neg	< 3	< 3	neg	10	< 10	<100
WSP 1104005	< 10	neg	< 3	< 3	neg	< 10	< 10	< 100
WSP 1104006	< 10	neg	3	< 3	neg	< 10	30	< 100

3) Polycyclic Aromatic Hydrocarbons (PAHs)

The levels of marker PAHs in three different lots of wood sterols are presented in the following table.

Lot No.	Benzo (a) pyrene (ppb)	Benzo (a) authracene (ppb)
WSP 1004004	0.4	0.1
WSP 1104005	0.4	0.2
WSP 1104006	0.4	0.1

The levels of Benzo (a) pyrene and Benzo (a) anthracene are insignificantly low and below the European Union established maximum levels of 2.0 ppb in oils and fats (EC No. 208/2005).

4) Aflatoxins

The following table presents the levels of aflatoxins G2, G1, B2, B1 in three different lots of wood sterols. No significant levels of these compounds were found.

	Aflatoxins (ppb)				
Lot No.	G2	G1	B2	B1	Total
WSP 1004004	< 0.1	< 0.1	< 0.1	< 0.1	< 0.4
WSP 1104005	< 0.1	< 0.1	< 0.1	< 0.1	< 0.4
WSP 1104006	< 0.1	< 0.1	< 0.1	< 0.1	< 0.4

5) Residual Solvents

The next table shows the levels of residual solvents in three representative lots of wood sterols.

Solvent Residues in Wood Sterols (mg/kg)

	Lot Number		
	WSP 1004004	WSP 1104005	WSP 1104006
Hexane	<0.5	<0.5	<0.5
Ethyl Acetate	<0.5	<0.5	<0.5
2-Butanone	<0.5	0.8	<0.5
Isopropanol	<0.5	<0.5	<0.5
Acetone	<0.5	<0.5	<0.5
Ethanol	<0.5	<0.5	<0.5
Methanol	2.8	<0.5	6.8

Units are mg/kg (ppm)

Solvent residues are within maximum limits established by European Union food regulations (Directives 92/115/CEE, 97/60/CE, 88/344/CEE). In the European Union, the maximum methanol level allowed in foods is 10 mg/kg (92/115/EEC). In the United States, tolerance levels of methanol residues have been established only for spice oleoresins (50 mg/kg) and for the hop extract used for the production of beer (2.2% by weight) (21 CFR 173.250). ICH harmonized guidelines for pharmaceutical products classifies methanol as a Class 2 solvent and accepts a maximum concentration of this substance in pharmaceutical products up to 3000 ppm (ICH Harmonized Tripartite Guidelines, 1997). All these methanol maximum limits are much higher than those found in ADM wood sterols.

2-Butanone is a substance authorized in the United States for use in foods as a flavoring agent and adjuvant at GMP levels (CFR 172.515). According to ICH guidelines for residual solvents in pharmaceutical products, 2-butanone is considered as Class 3 solvent, allowing levels up to 5000 ppm without justification (ICH Guidelines Q3C, 1997).

6) Pesticide Residues

Wood sterol lot nos. WSP 1004004, WSP 1104005 and WSP 1104006 were tested for the presence of 62 different potential pesticide residues, including those banned in the U.S. and the European Union. None of these pesticides were

detected in any of the samples. The corresponding laboratory report is presented as Appendix D.

7) Dioxins

Appendix E shows the results of dioxin analyses conducted in wood sterol lot numbers WSP 1004004, WSP 1104005 and WSP 1104006. Total TEQ values, determined by using WHO toxic equivalent factors, are below the maximum level of <0.75 pg/g established by European Union Regulation (EC) No. 2375/2001 for vegetable oils.

8) Terpenoids

The chief terpenoid compounds that according to the literature are commonly found in pine trees (5) have been analyzed in wood sterol esters, the product to be provided to our customers. Although no maximum allowed limits have been established for these compounds, as indicated on the following table, none of these potentially deleterious substances were detected in the tested materials.

Analysis of Main Terpenoid Compounds in Wood Sterol Esters

Sample ID	Lot P260404	Lot P270803
alpha-Pinene, mg/kg	nd	nd
alpha-Terpinene, mg/kg	nd	nd
p-Cymene, mg/kg	nd	nd
Limonene, mg/kg	nd	nd
Cineole, mg/kg	nd	nd
gamma-Terpinene, mg/kg	nd	nd
Terpinolene, mg/kg	nd	nd
Fenchol, mg/kg	nd	nd
Camphor, mg/kg	nd	nd
Isoborneol, mg/kg	nd	nd
Borneol, mg/kg	nd	nd
Terpinen-4-ol, mg/kg	nd	nd
alpha-Terpineol, mg/kg	nd	nd
4-Allylanisole, mg/kg	nd	nd
trans-Anethole, mg/kg	nd	nd

nd = None Detected
Detection limit for each compound is 2 mg/kg

IV BASIS FOR GRAS DETERMINATION FOR THE USE OF PLANT STEROLS AND PLANT STEROL ESTERS IN AN EXPANDED RANGE OF FOOD CATEGORIES

A) Updated Safety Information

As noted above, plant sterols and sterol esters have been the subject of numerous safety studies. These studies have involved sterols and sterol esters derived from both vegetable oils and tall oils. Below is a summary of the safety literature previously submitted to FDA and some more recent safety studies.

1) Safety Overview

On January 11, 1999, the Lipton Company notified the U.S. FDA of its determination that plant (vegetable oil) sterol esters were Generally Recognized as Safe (FMF 625). This determination was based on an extensive review of the scientific literature and the opinion of an expert panel that evaluated all the existing toxicological and safety information up to 1999. After review of this file, FDA had no objections for the marketing of sterol esters as ingredients in oil spreads (FDA letter from A.M. Rulis to D. Dwyer dated 4/30/99). Lipton's GRAS panel was the same expert panel that reviewed the present ADM GRAS affirmation for the expansion of food categories; the subject of this new notification. In 1999, this panel concluded that the extensive human safety information on phytosterol arising from both the free sterol and the sterol ester literature was pertinent to conclude the human safety of phytosterols and for establishing safe exposure limits. Furthermore, the panel concluded that an acceptable daily intake (ADI) was 130 mg/kg/day (as free sterol). For a 70 kg reference man, this level translates to an ADI of 9.1 g/day. It was also established in this report, and later acknowledged by the FDA, that independent of the phytosterol chemical form (free or esterified), the active form, after intestinal hydrolysis, was free sterols. Stanol esters have also been recognized as GRAS by the agency (McNeil, FMF 626).

Further safety assessment of plant sterols and sterol esters, including those derived from tall oil (wood sterols), have been conducted in the U.S. during 2000-2002 by various scientific expert panels. As a result, GRAS status for a broad range of food categories has been attained for plant sterol and sterol esters produced by Novartis Consumer Health (GRN Notice No. 000039), the Procter & Gamble Company (GRN Notice No. 000053), Cargill Inc. (GRAS Notice No. 000048), Archer Daniels Midland Company (GRAS Notice No. GRN 000061), and Teriaka Ltd. (GRAS Notice No. GRN 000112).

This new GRAS assessment for the use of ADM plant sterols in expanded food categories by an expert panel is in line with previous safety evaluations.

In Europe, the safety of plant sterols and plant sterol esters has been reviewed extensively on several occasions during 2002-03 by the Scientific Committee on Foods (SCF, Ref. 6-11), and more recently toward the end of 2003, by a Scientific Panel of the European Food Safety Authority (EFSA, Ref. 12). A copy of this latest report by EFSA is presented as Appendix F. As a result, the marketing of plant sterols (from vegetable oils and wood sterols) added to a variety of food categories has been authorized by the Directorate General for Health and Consumer Protection (DGSANCO) in the European Community. In addition, the safety of these products has been confirmed recently by a group of independent scientific experts who met in Stresa, Italy, in 2001 to discuss the efficacy and

safety of plant stanols and sterols in the management of blood cholesterol levels (Katan et al. 2003, Ref. 1).

The main conclusions of all these scientific evaluations has been that sterols are safe for human consumption with only one recommendation; to keep an adequate consumption of dietary carotenoid sources (fruit and vegetables) to compensate for an observed, clinically irrelevant, decrease in β-carotene levels. The potential effect of phytosterols on carotenoids and fat soluble vitamins is discussed in greater detail in Section IV A (2)-(3) below.

2) Literature Update

The most relevant publications since the safety evaluations submitted to FDA for the aforementioned GRAS notifications have been: a) A comprehensive review summarizing the deliberations and conclusions of 32 experts on lipids, nutrition and heart disease from various countries who met in Stresa, Italy on March 7-9, 2001, under the auspices of the Nutrition Foundation of Italy, to discuss the efficacy, safety and future of plant sterols and plant sterol esters (Katan et al. 2003, Ref. 1); and b) A long-term clinical study by Hendricks et al. (2003) on the safety of long-term consumption of plant sterols in humans (13).

In the Stresa Workshop, based on a meta-analysis of 41 clinical trials, it was concluded that intake of 2 g/day of plant sterols/stanols reduced low-density

lipoprotein cholesterol (LDL-cholesterol) by 10% and that higher sterol intakes added little. This amount can be increased or decreased depending on the composition of the diet and/or the food matrix used for sterol enrichment. Since previous reports showed concerns about the negative effect on the absorption of fat soluble vitamins, a meta-analysis of 10 to 15 trials per vitamin revealed that plasma levels of vitamins A and D are not affected by the consumption of plant sterols/stanols. Alpha carotene, lycopene and vitamin E levels remained stable relative to their carrier molecule, LDL. However, β-carotene levels have consistently declined, within normal levels in most studies, but adverse effects of this phenomenon have not been shown or been expected. It was also indicated that sterol-enriched foods can increase plasma sterols levels, particularly in individuals with phytosterolemia. However, the increased risk of increasing atherosclerosis due to higher levels of blood sterols in patients with homozygous phytosterolemia is believed to be only hypothetical. Regarding a safe upper level of sterol intake, it is also clear that maximum efficacy is around 2-3 g/sterol/day. This is in fact the basis for which EU regulatory bodies such as the SCF and EFSA have recommended in Europe a maximum consumption of 2-3 g/sterol per day. However, as discussed in this review, the 2-3 g/day has been set arbitrarily on efficacy and not on safety. There is no evidence that intakes higher than 2-3 g/day cause any harm, as can be the case of consumers who may be ingesting a wide range of products enriched with sterol/stanols. In closing, the Stresa Workshop participants recognized that the safety testing of sterols and stanols has exceeded that of ordinary food stuffs that are eaten widely and generally

considered as safe. Furthermore, adverse effects of the absorption of plant sterols into the circulation appear largely hypothetical, and adverse health outcomes of a decrease in beta-carotene levels in plasma are only speculative and not of major concern.

Hendricks et al. (2003) long-term clinical study (13) is relevant because previous studies in humans had focused mainly on the efficacy and had been of short duration and with a limited number of subjects. The present investigation, using a randomized double-blind placebo-controlled parallel trial, addressed both safety and efficacy of long-term consumption of sterols in 185 subjects consuming for a period of one year a 20 g spread enriched with 1.6 g plant sterol esters. Outcome measures included efficacy markers such as total LDL-cholesterol, a large range of safety parameters and reporting of adverse events. Consumption of plant sterols consistently lowered total and LDL-cholesterol during the one year period, on average 4 and 6%, respectively. However, blood carotenoid concentrations changed over time. Sterol intake reduced lipid adjusted α- and β-carotene concentrations by 15-25% after one year relative to control. Lipid-adjusted fat soluble vitamins remained unchanged. Sterol concentration in serum increased from 2.76 to 5.31 (μmol/mmol total cholesterol) for campesterol and from 1.86 to 2.45 μmol/mmol total cholesterol) for β-sitosterol. The increase in total plant sterol concentration in red blood cells (5.29-9.62 μg/g) did not affect red blood cell deformability. Hormone levels in males (free and total testosterone) and females (luteinizing hormone, follicle stimulating hormone, β-estradiol and

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progesterone), as well as all clinical chemical and hematological parameters measured were unaffected. Adverse event reporting was not different between subjects consuming the control product vs. the sterol containing product. It is concluded in this investigation that consumption of plant sterol esters-enriched spreads is an effective way to consistently lower blood cholesterol and is safe to use over long periods of time.

Other relevant papers in the literature are either toxicological studies using animal models confirming the safety of sterols and sterol oxidation products (14-15) or short term clinical trials showing the efficacy of plant sterols and its various bioavailabilities when used in different food matrices such as milk, yogurt, bread and cereal (16-17).

One of the animal toxicological studies consists of the safety assessment of sub-chronic oral toxicity of phytosterol esters (14). In this study, rats were fed diets containing phytosterol esters at levels of 0, 0.16, 1.6, 3.2 and 8.1% (w/w) in the diet for 90 days. After a thorough clinical and pathological evaluation, there were no treatment-related changes that were considered to be of toxicological significance. Therefore, a nominal phytosterol ester concentration of 8.1% was considered to be the no-observed adverse effect level (NOAEL). This was equivalent to 6.6 g/kgBW/day of phytosterol ester, or to 4.1 g/kgBW/day of free sterol.

The other toxicological study addressed the potential genotoxicity and sub-chronic toxicity of phytosterol oxides that may occur in very small amounts under very high temperatures, as a result of phytosterol oxidation (15). The genotoxicity and sub-chronic toxicity of these compounds was assessed in a series of in vitro genotoxicity assays (bacterial mutation, chromosome aberrations and micronucleus) and a sub-chronic feeding study in the rat. It was found that a phytosterol oxide concentrate (approximately 30% phytosterol oxides) did not possess genotoxic potential and no obvious evidence of toxicity when administered to rats for 90 consecutive days. It was concluded in this investigation that phytosterol oxides raise no concerns for human safety.

The data from animal studies suggesting negative effects of high sterol intakes on stroke-prone spontaneously hypertensive (SHRSP) rats (18) and on the modulation of growth of estrogen-responsive breast cancer cells in ovariectomized athymic mice (19) are limited and inconclusive, particularly regarding their significance to human health. Ratnayake et al. (18) reported that plant sterols and plant stanols shorten the lifespan of SHRSP rats and provoke hemorrhagic stroke. These results are, however, equivocal, because the same group of investigators have also indicated that other vegetable oils, in particular olive oil, also shorten the lifespan of SHRSP rats, despite lower amounts of phytosterol in those oils than in canola or corn oil. In addition, SHRSP rats, in contrast to normal rats, absorb excessive amounts of both sterols and stanols and therefore may not be an appropriate model to reflect what may occur in humans whose intestinal absorption of sterols, and particularly of stanols, is very limited.

As discussed in a recent review by Kritchevsky and Chen, these observations in SHRSP rats should not represent a safety concern (20). Regarding modulation of cancer growth, Ju et al. (19) studied the in vitro and in vivo effect of β-sitosterol and β-sitosterol glucoside on the growth of estrogen-responsive breast cancer cells in vitro and in ovariectomized athymic mice. It was found that β-sistosterol can stimulate cancerous growth in vitro. However, in vivo, as part of the diet, β-sitosterol reduced tumor growth. Due to the experimental nature of these latter animal studies, they are considered irrelevant for this ADM petition.

Taken together, the newly generated data has confirmed the safety of plant sterol/sterol esters (derived from both vegetable oils and tall oils) consumption during long periods of time. However, as confirmed by the latest studies, a consistent observation has been the decrease in plasma carotenoid levels; particularly β-carotene (13, 16, 21). This decrease in plasma carotenoids has no clinical significance and can be corrected by increasing the consumption of green-leafy vegetables, fruits and other important dietary sources of carotenoids (22).

3) Potential Adverse Effects

As previously discussed, the main safety concerns of an increased consumption of phytosterols have been elevation of plasma sterols that may lead to atherosclerosis and impairment of the absorption of fat soluble vitamins, including a decrease in plasma levels of carotenoids.

Metabolically, sterols are minimally absorbed into the circulation, except in individuals suffering from a genetic condition known as phytosterolemia. Furthermore, atherosclerosis due to elevated levels of plasma sterols has not been clinically proven.

In regard to the utilization of fat soluble vitamins, several studies have shown that increased intakes of phytosterols do not impair their intestinal absorption. However, one consistent finding in these studies has been a significant decrease in plasma carotenoid levels, generally attributed to an impaired intestinal absorption of these compounds.

Since considerable attention has been focused on the impact of sterol consumption on the plasma levels of carotenoids, we address this subject below in more detail.

Several human studies have shown either an insignificant decrease in the plasma carotenoid levels or a significant decrease that becomes insignificant when adjusted to changes in the plasma lipid profile (23). However, when looking at particular carotenoids, there is a consistent and clear tendency for a decrease, even after correcting for lipid changes, in the plasma levels of α and β-carotenes and lycopene (24-25). Changes in the plasma levels of other carotenoids or fat soluble vitamins have been inconsistent (23). It appears, then, that only the more hydrophilic carotenoids, such as α and β-carotene and lycopene are affected by

the ingestion of sterols. Hydrophilic carotenoids need to be solubilized in the lipid core of the micelles in the gut lumen for proper intestinal absorption (26). This is a somewhat similar mechanism for the effect of sterols on intestinal cholesterol absorption, therefore, it is likely that carotenoids are equally affected and thus their plasma levels decrease. Given this as a fact and considering that carotenoids can be dietary precursors of vitamin A, the important question is whether this phenomenon has any nutritional or public health significance, particularly in the long term. In this regard, the following are important considerations:

1 - Despite the decrease in carotenoid levels, such values are still within the normal range and even above what is considered the average normal values (26). This can be illustrated by using the data submitted by Unilever to the SCF of the European Union regarding the changes observed in β-carotene after 26 and 52 weeks of consumption by adults of a fat spread containing 8% (w/w) phytosterols (6). For comparison, average and range reference β-carotene plasma values have been included as part of the table.

Changes on Plasma β-Carotene after One Year
Consumption of Sterols Compared to Normal Reference Values

Time	β-Carotene[a] (μg mole)	Average Reference Value (M/F)[b] (μg mole)	Reference Range[b] (5-95th percentile) (μg mole)
Week 0	0.41 ± 0.22		
Week 26	0.32 ± 0.18		
Week 52	0.31 ± 0.19	0.22/0.28	0.09-0.91

a - Adapted from Unilever (Ref. 6).
b - From Olson, J., 1999. (Ref. 26); M: Adult males, F: Adult females.

It can be observed in this Unilever study that after one year of phytosterol consumption by adult subjects, there is a 25% drop in plasma β-carotene. The β-carotene value, however, even at 52 weeks is above the plasma average reference value for both men and women in a normal population and well within what is considered a normal plasma β-carotene range (5-95th percentile). No other levels of vitamins or other carotenoids were affected in this study. The same phenomenon has been observed in a more recent study by Maki et al (27). In this investigation, blood carotenoid levels remained within normal limits after the consumption by adult subjects of 1.1 g/day or 2.2 g/day of plant sterols for a period of five weeks.

2 - When consuming phytosterols, the actual plasma levels of Vitamin A (retinol), as well as of other fat soluble vitamins, are not altered (25). In fact, the intestinal absorption of Vitamin A (as retinyl palmitate), and also the absorption of other fat soluble vitamins, is not affected when given to humans as part of a fat load test in the presence of sterols (28).

3 - Vitamin A plays an essential role in growth, development and maturation. However, carotenoids are not needed by mammals, with adequate preformed Vitamin A in the diet, and therefore they cannot be considered essential (26). In fact, the contribution of carotenoid to Vitamin A nutrition is very low. The intestinal dietary absorption of carotenoids is only 10-50%. Furthermore, only a small portion of those absorbed are converted to retinol. Different carotenoids,

depending on their molecular structure, have different biological activities. For practical purposes, the conversion of mixed carotenoids as they occur in the diet is considered to be only 1/12 of the preformed Vitamin A activity (26). Thus, it can be assumed that a 25% carotenoid loss (as in the previous Unilever study) due to failure of intestinal absorption represents only a potential 2% contribution to Vitamin A nutrition. In theory, this would be the portion that is being lost by the body due to the sterol consumption. Considering the RDA for Vitamin A is 900-1300 μgRE/day for the United States adult population (29), a 2% difference is only about 18-26 μg of dietary Vitamin A, which can be easily compensated from dietary sources (e.g. one cup of unfortified whole milk has 101 μg of Vitamin A). Again, when there is enough dietary preformed Vitamin A, this 2% is not critical.

4 - Vitamin A is stored in the liver and it is not easily depleted. Normal liver stores range from 20-300 μg/g liver (30). Thus, an adult liver weighing 1.5 kg will contain about 240,000 μg (0.24 g) of stored Vitamin A (considering an average liver Vitamin A concentration of 160 μg/g). If the half life (t ½) of stored Vitamin A is 128-156 days (average 142 days) it would take 14.2 months (more than 1 year) for liver stores to reach deficient levels (three half life equivalents before reaching <20 μg retinol/g liver) (30). In fact, actual Vitamin A deficiency studies in adult humans have shown that it takes up to 2 years to reach a deficiency state when consuming a Vitamin A depleted diet (31). It would be highly unlikely to find these severe conditions in a normal setting. Thus, a potential 2% loss on Vitamin A nutrition, due to the observed

decrease in carotenoids, becomes insignificant when considering the depletion rate of Vitamin A.

5 - The observed changes in plasma levels of carotenoids or fat soluble vitamins have never been associated to any functional alterations or any pathological condition. Thus, these changes can be considered clinically unimportant and therefore of no significant health concern (1). This is a very important consideration from the biological perspective.

6 - According to a recent report by the Institute of Medicine (IOM), in the United States Vitamin A deficiency is not a public health concern (29). On the contrary, based on a link between carotenoid supplementation and increased incidence of lung cancer in certain segments of the population, excessive carotenoids intake has recently been a concern of the IOM and European health authorities, and thus a target for reduction (29). Therefore, in the United States, there is not an at risk population group that could easily become deficient in this vitamin. From the dietary perspective, in the United States, Vitamin A sources are primarily preformed Vitamin A from fortified foods such as milk, yellow margarines and breakfast cereals.

7 - One important consideration is that sterol-enriched products are aimed and consumed primarily by hypercholesterolemic adult individuals. The nature of

their customary diet will most probably be both high in cholesterol and in preformed Vitamin A. Cholesterol rich foods are normally also high in Vitamin A and in fat (e.g. eggs, organ meats, whole milk, etc.). These individuals would have ample Vitamin A stores and it would be unlikely for these subjects to be at risk of Vitamin A deficiency due to their ingestion of sterol enriched products.

8 - Recently, Noakes et al (22) have shown that the decrease in plasma carotenoid levels observed when consuming phytosterol-enriched foods, can be compensated by an adequate consumption of fruits and vegetables rich in carotenoids.

Given the above scientific analysis, it can be concluded that the observed decrease in carotenoids should not represent a public health risk in the United States.

4) Estimation of Total Sterol and Sterol Ester Consumption from All Food Categories

The total potential consumption of sterol equivalents in all proposed food categories was determined statistically by using the USDA Continuing Survey of Food Intakes by Individuals (CSFII) 1994-96, 98 database (released in 2000) serving sizes established by the Code of Federal Regulations (Part 101.12) and the SAS software (SAS system V9, SAS Institute, Cary, NC). Means and 90th percentiles were determined for individuals (users only) in the population divided in three age groups, as follows: children (3-11 y old), teenagers (12-19 y old) and adults (>20 y old). Infants (<2 y of age) were not included. Calculations were made using a level of

addition of sterol of 0.4 g (400 mg) of sterol equivalent per serving, except that for vegetable oils, incorporation rates were considered at a level of 4%, and for fruit/vegetable juices, the incorporation rate was 1 gram per serving. The consumption of edible oil was estimated consistent with information previously provided by ADM to the FDA on February 24, 2003, as part of the GRAS notification of Enova oil (GRAS notice No. 000115). Since Enova oil, a diacylglycerol oil, is considered to be a replacement for vegetable oil, consequently it is intrinsically included in these calculations. A summary of the results obtained in this sterol consumption analysis is presented in the following table. A detailed report, including a complete listing and food codes of individual food items used in the calculations, is presented as Appendix G.

Total Estimated Consumption of Sterols (both vegetable and tall oil derived) (Mean and 90th Percentile) in Different Age Groups from all Proposed Food Categories

	n*	Mean	**90th Percentile**
Children (3-11 years old)			
Number of Servings/day	6268	4.06	7.11
Grams of sterol/person/day	6268	1.62	2.84
Grams/kgBW/day	5868	0.067	0.123
			(123 mg/kgBW/day)
Teenagers (12-19 years old)			
Number of Servings/day	1372	5.21	9.83
Grams of sterol/person/day	1372	2.08	3.93
Grams/kgBW/day	1348	0.035	0.067
			(67 mg/kgBW/day)
Adults (≥ 20 years old)			
Number of Servings/day	9174	5.23	9.72
Grams of sterol/person/day	9174	2.09	3.89
Grams/kgBW/day	9013	0.029	0.055
			(55 mg/kgBW/day)

* n values differ due to availability of body weight information

Notice in the above table that the total potential consumption of sterols from all proposed food categories, at the 90th percentile, is below the ADI established in the Lipton petition of 130 mg/kgBW/day in all age groups under consideration. For a 70 kg reference adult individual, the observed sterol intake of 55 mg/kgBW/day at the 90th percentile would be equivalent to 3.9 g sterol/day.

However, it should be acknowledged that higher consumption can occur due to directed food product selection.

B) Safety Information on the Use of Sucrose Fatty Acid Esters (SFAE)

1) Use of SFAE as an Emulsifier in Specified Sterol-Enriched Products

The addition of phytosterols to some food categories specifically milk type products, which includes soy milk, ice cream and cream substitutes (category 5) and fruit/vegetable juices (category 9) may require, for functionality, the addition of an emulsifier. One of the substances to be used preferentially as an emulsifier in these food products is Sucrose Fatty Acid Ester (SFAE), an approved food additive for certain food applicants (21 CFR 172.859). The phytosterols, either from edible vegetable oil or from tall oils, are blended in a 1:1 ratio with SFAE. This product, known as Euchol™, is marketed by ADM as CardioAid-WD phytosterols and CardioAid-CZ phytosterols under license of Eugene Science, Korea.

Both, safety and dietary consumption of SFAE in sterol enriched products derived from either edible vegetable oils or from tall oil, have been evaluated as part of this application. A full report of this evaluation has been appended to this document (see discussion of estimated consumption in Section IV-B, 2 below). Based on safety considerations, it is concluded in such report that the use of

SFAE in an up to 1:1 ratio between SFAE and sterol (0.4 g SFAE:0.4 g Sterol) is safe for the intended use in the aforementioned 2 food categories. [Note that this sterol use level with SFAE is lower than the requested use level of 1 gram per serving for free sterols/sterol esters in juice products, as indicated in the respective section I-D.]

A recent clinical trial using a similar mixture of sterol:SFAE in a 1:1 ratio (EuChol™) has demonstrated the effectiveness of this formulation in lowering blood cholesterol levels (Eugene Science, unpublished report, 2005). In this randomized, cross-over study, 24 healthy adults were given, as a single dose, a 1:1 mixture of phytosterols and SFAE in amounts of 200 mg, 300 mg and 500 mg of sterols and SFAE, respectively. Using isotopic techniques, it was shown that this formulation reduced cholesterol absorption by 23% at a dose of 300 mg phytosterol/300 mg SFAE and by 32% when the dose was increased to 500 mg phytosterol/500 mg SFAE. The highest dose of SFAE used in this investigation is higher than the level of SFAE proposed in the present GRAS affirmation (400 vs. 500 mg/serving). No adverse events were reported during the short duration of the study.

2) Estimated Consumption of SFAE in Sterol-Enriched Food Categories

The estimation of consumption of SFAE was conducted following the same statistical approach described above, but only on a subset of food items

(Categories 5 and 9) whose addition of sterols requires emulsification. A complete review of the technical information and safety of SFAE, including the estimated intake in the proposed categories requiring SFAE is presented as Appendix H. The level of SFAE used in the calculations was a 1:1 ratio of sterol:SFAE. That is, each serving of the proposed food item was considered to contain 0.4 g of free sterols and 0.4 g of SFAE. The use of the emulsified product may be used in place of free sterols in the respective categories, so the overall consumption calculation provided in section IV-A4 above will be a maximum. A summary of the results of the consumption analysis of SFAE follows.

Estimation of Sucrose Fatty Acid Ester Intake in Specified Sterol-Enriched Food Categories (Categories 5 & 9) Requiring Emulsification*

	n**	Mean	**90th Percentile**
Children (3-11 years old)			
Number of Servings/day	2913	0.80	1.56
Grams SFAE/Person/day	2913	0.32	0.62
Grams SFAE/kgBW/day	2715	0.014	0.026
			(26 mg/kgBW/day)
Teenagers (12-19 years old)			
Number of Servings/day	495	1.12	2.08
Grams SFAE/person/day	495	0.45	0.83
Grams SFAE/kgBW/day	485	0.008	0.016
			(16 mg/kgBW/day)
Adults (≥ 20 years old)			
Number of Servings/day	3886	2.41	4.50
Grams SFAE/person/day	3886	0.96	1.80
Grams SFAE/kgBW/day	3818	0.013	0.026
			(26 mg/kgBW/day)

* 1:1 proportion ratio of sterol:SFAE blend (0.4 g of sterol and 0.4 of SFAE)
** n values differ due to availability of body weight information

As indicated in Appendix H, the ADI established by JECFA (32) and more recently by an EFSA safety review panel (33), has been set at 30 mg/kgBW/day for SFAE. Based on this cut-off point, the 90th percentile consumption values of SFAE for all target age groups are below this 30 mg/kgBW/day limit.

Mitsubishi Chemical Corporation has also estimated that the cumulative exposure of SFAE arising from all uses in the United States, including its use as an approved food additive (21 CFR 172.859), would be 60 mg/person/day (page 2 of GRAS letter GRN 000129, Appendix H). For a 60 kg reference person this intake of SFAE would be equivalent to 1 mg/kgBW/day. This 1 mg value is supported by available ADM market research on the use of emulsifiers, which indicates an annual use of SFAE in foods in the United States of 600 metric tons (34). By dividing this volume of SFAE by the projected U.S. population for 2005 by the Census Bureau of about 296,000,000 inhabitants, it can be estimated that the intake of this compound is only approximately 6 mg/person/day (0.1 mg/kgBW/day), well below the 60 mg/person/day originally estimated by Mitsubishi Chemical Corporation. For practical purposes, however, if we consider 1 mg/kgBW/day as the estimated cumulative consumption of SFAE from all sources and we add this additional amount to the 26 mg/kgBW/day, the highest 90th percentile value estimated by adding the proposed food categories, the total consumption becomes 27 mg/kgBW/day. This is equivalent to 1.62 g/person/day (27 mg x 60 kg reference person), which is below the NOAEL value of 2 g of SFAE/day, based on clinical studies.

V Conclusion

Based on the information presented here, it can be concluded that plant sterols and sterol esters, derived from either vegetable oils or from tall oil (wood sterols), are GRAS for the intended use in an expanded range of food categories. It can also be concluded that the addition of sucrose fatty acid ester (SFAE) in certain sterol-enriched food applications which require emulsification raises no safety issue. ADM bases its GRAS conclusion on a critical review of the sterol literature, all technical information presented here, and the estimated consumption levels of sterol and SFAE which are below established ADI values of 130 mg/kgBW/day and 30 mg/kgBW/day, respectively.

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VII Appendices

Appendix A

Appendix A

Sterol GRAS Notices Issued by FDA to Several Companies

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

April 30, 1999

Daniel R. Dwyer
Kleinfeld, Kaplan and Becker
1140 Nineteenth Street, N.W.
Washington, DC 20036-6601

Re: Food Master File 000625

Dear Mr. Dwyer:

The Food and Drug Administration (FDA) is responding to the submission, dated January 11, 1999, that you made on behalf of Lipton. FDA received this submission on January 12, 1999, and designated it as Food Master File 000625.

The subject of Lipton's submission is vegetable oil sterol esters. The submission informs FDA of Lipton's view that vegetable oil sterol esters are generally recognized as safe (GRAS) for use in vegetable oil spreads at levels up to 20% to supplement the nutritive value of the spread, and to help structure the fat phase and reduce the fat and water content of the spread. According to Lipton, the use of vegetable oil sterol esters in vegetable oil-based spreads is intended to help maintain healthy cholesterol levels as part of a diet low in saturated fat and cholesterol. The basis for Lipton's view that this use of vegetable oil sterol esters is GRAS is scientific procedures (21 CFR 170.30(b)). The submission includes the findings of a panel (Lipton's GRAS panel) of individuals who evaluated the data and information that are the basis for Lipton's GRAS determination. Lipton considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food.

According to Lipton, β-sitosterol, campesterol, and stigmasterol are the main sterol components of vegetable oil sterol esters. These sterols, which are obtained from vegetable oil distillates, are re-esterified with sunflower oil-derived fatty acids to improve their solubility. Lipton's submission describes the manufacturing process for vegetable oil sterol esters and proposes food grade specifications. Based on the use of vegetable oil sterol esters in vegetable oil spreads at levels up to 20%, Lipton estimates that consumer exposure to vegetable oil sterol esters would be approximately 1800 to 4800 mg/person/day. This intake of sterol esters corresponds to an estimated dietary intake of the sterol components of approximately 1100 to 3400 mg/person/day (i.e., approximately 18 to 57 mg/kg bw/day for a 60 kg adult). Lipton also estimates that this consumption from the use of vegetable oil sterol esters would result in a 4- to 14-fold increase in consumption of these substances relative to their current intake from other food sources.

Lipton describes published and unpublished absorption, distribution, metabolism, and excretion studies in animals and humans. Based on these studies, Lipton concludes that vegetable oil sterol esters are hydrolyzed to free sterols in the gastrointestinal tract. Lipton also concludes that absorption of free sterols ranges from approximately 4 to 10 per cent in animals and humans, depending on the sterol, and that the phytosterols that are absorbed are rapidly eliminated from the body.

Lipton describes published and unpublished human studies that were conducted in support of the safety and efficacy of phytosterols in reducing serum cholesterol levels. Lipton's GRAS panel concluded that these human studies conducted with free phytosterols are pertinent to the evaluation of vegetable oil sterol esters because vegetable oil sterol esters are hydrolyzed in the gastrointestinal tract to free phytosterols and fatty acids. The data described in some of the published studies supported the approval of the drug *Cytellin*, which was marketed for many years. The sterol composition of *Cytellin* was 80 - 90 per cent β-sitosterol and therapeutic levels ranged from 9,000 to 30,000 mg of β-sitosterol per day.

The minimal absorption of vegetable oil sterol esters, coupled with their lipophilic nature, raises the question of the potential effect of vegetable oil sterol esters on the uptake of fat-soluble vitamins (Vitamins A, D, E, and K). Lipton addresses this potential effect in two ways. First, Lipton describes a published human study that includes a measurement of serum levels of Vitamins D, E, and K after 3.5 weeks of daily intake. This measurement showed some decrease in serum levels of Vitamin K at the highest concentration tested (i.e., 3.2 g free sterols/day). Second, Lipton analyzes published information about Vitamin K, including its high lipophilicity, its rapid half-life in serum, its low level of storage in the body (and corresponding close relationship to the daily diet), its recognizable signs of deficiency, and the generally short time period for developing symptoms of Vitamin K deficiency. Based on this analysis, Lipton draws two conclusions: (1) Symptoms of Vitamin K deficiency can be used to assess the potential effect of vegetable oil sterol esters on the uptake of Vitamin K; and (2) symptoms of Vitamin K deficiency are a sensitive indicator for potential effects of vegetable oil sterol esters on the uptake of all the fat-soluble vitamins. Following this analysis, Lipton evaluates published clinical studies conducted with plant sterols with a daily intake ranging from 3 grams to 25 grams and a duration ranging from 20 weeks to 260 weeks. Based on this evaluation, Lipton both concludes that the absence of reported clinical signs of Vitamin K deficiency is evidence that there was no notable effect on Vitamin K status in these studies and infers that the absence of effects on Vitamin K status is evidence that vegetable oil sterol esters will not have an effect on the uptake of fat-soluble vitamins other than Vitamin K.

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Lipton describes a published uterotrophic assay and an unpublished two-generation reproduction study in rats. Based on these studies, Lipton concludes that vegetable oil sterol esters do not cause adverse reproductive effects. Lipton also describes a 13-week rat feeding study that has been discussed at an international scientific meeting. Based on this study, Lipton concludes that a dietary intake of approximately 3900 mg/kg bw/day did not result in any treatment-related effects in the rat. Lipton concludes that there is no need to investigate the potential carcinogenicity of vegetable oil sterol esters based on the lack of adverse effects (including pathology) in the 13-week rat feeding study; the lack of genotoxicity in unpublished genotoxicity studies; the minimal absorption and rapid elimination of phytosterols from the body; and the absence of structural alerts that would predict toxicity of vegetable oil sterol esters. Lipton's submission includes a letter from the National Toxicology Program (NTP), in which NTP has concluded, based in part on the results

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of data submitted by Lipton to NTP, that NTP will not proceed with its proposal to conduct multigeneration reproductive toxicity tests and chronic/carcinogenicity testing with β-sitosterol as a marker for saw palmetto.

FDA has evaluated the information in Lipton's submission as well as other available data and information, including the *Cytellin* file that is available at FDA's Center for Drug Evaluation and Research. In addition, FDA went to the office of Kleinfeld, Kaplan and Becker and evaluated certain data and information that were reviewed by Lipton's GRAS panel and by the NTP. Based on its evaluation, the agency has no questions at this time regarding Lipton's conclusion that vegetable oil sterol esters are GRAS under the intended conditions of use. Furthermore, FDA is not aware of any scientific evidence that vegetable oil sterol esters would be harmful. The agency has not, however, made its own determination regarding the GRAS status of the subject use of vegetable oil sterol esters. As always, it is Lipton's continuing responsibility to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

An evaluation that a use of a food ingredient is safe is a time-dependent judgment that is based on general scientific knowledge as well specific data and information about the ingredient. The intended use of vegetable oil sterol esters to help maintain healthy cholesterol levels as part of a diet low in saturated fat and cholesterol exemplifies a recent trend in the food industry to develop food ingredients that have a nontraditional function. The evolving scientific knowledge about such ingredients in the context of changing dietary patterns, including long-term nutritional implications, amplifies the time-dependent nature of any safety evaluation. Accordingly, the agency believes that it would be both prudent and responsible for Lipton to continue to monitor, through scientific studies or otherwise, consumers' dietary exposure to vegetable oil sterol esters and the long-term nutritional implications for individuals in all age groups who routinely consume the ingredient. In this regard, we were pleased to receive Lipton's letter dated April 28, 1999, which (1) describes initiatives that Lipton intends to have in place to ensure that its product is well understood by both consumers and health-care professionals and to encourage an ongoing exchange of information about the product once it is marketed; (2) describes ongoing clinical studies that are part of Lipton's continuing commitment to evaluate its product; and (3) states Lipton's commitment, as part of its ongoing discussion with FDA, to communicate with FDA as relevant information is developed from these initiatives and studies.

Finally, we have been advised by the Office of Food Labeling (OFL) in the Center for Food Safety and Applied Nutrition that the proposed claim. "Helps promote healthy cholesterol levels as part of a diet low in saturated fat and cholesterol" falls within the purview of structure/function claims. However, as stated in OFL's letters of April 6, 1999, and April 20, 1999, the statement of identity for Take Control™ does not comply with the prominence requirements of 21 CFR 101.3(a) and 101.3(d). We would expect you to bring the statement of identity into compliance with the regulations. OFL is sending you a letter responding to the arguments in your April 20, 1999, letter discussing this issue. OFL has no other objection to your label.

Sincerely,

(b) [redacted]

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

U. S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Premarket Approval

Agency Response Letter
GRAS Notice No. GRN 000039

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Washington, DC 20204

April 24, 2000

Judith A. Weinstein
Novartis Consumer Health, Inc.
560 Morris Avenue
Building F
Summit, NJ 07901-1312

Re: GRAS Notice No. GRN 000039

Dear Ms. Weinstein:

The Food and Drug Administration (FDA) is responding to the notice, dated January 28, 2000, that you submitted in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received your notice on January 28, 2000 and designated it as GRAS Notice No. GRN 000039.

The subject of your notice is tall oil phytosterols. The notice informs FDA of the view of Novartis Consumer Health, Inc. (Novartis) that tall oil phytosterols are GRAS, through scientific procedures, for use as a nutrient in vegetable oil spread to reduce the absorption of cholesterol from the gastrointestinal tract at a level up to 12% free phytosterols.

Identity, method of manufacture, and specifications

Your notice describes the manufacturing process for tall oil phytosterols, which are extracted from tall oil soap (a by-product of the pulping process used for coniferous trees in North America and Europe) using organic solvents. The extracted phytosterols are subjected to a complexation-washing process that removes the bulk of the organic material, and the crude phytosterols are then dissolved in alcohol and crystallized. The resulting product, tall oil phytosterols, is predominantly a mixture of four phytosterols (i.e., sitosterol, sitostanol, campesterol, and campestanol). Your notice includes food grade specifications for tall oil phytosterols.

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Dietary exposure

According to your notice, the major components of tall oil phytosterols already are present in other vegetable oil based spreads that have a similar intended use.[1] For this reason, you assert that the ingredient tall oil phytosterols provides an additional choice for consumers seeking to maintain a healthy cholesterol level through the consumption of vegetable oil spread. Thus, the intended use of tall oil phytosterols is a substitutional use that would not increase dietary exposure to its main components.

Report of Novartis' "GRAS Panel"

The notice includes the findings of a panel of individuals (Novartis' GRAS panel) who evaluated the data and information that are the basis for Novartis' GRAS determination. Novartis considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food.

In its report, Novartis' GRAS panel compares the composition of tall oil phytosterols to that of the two related ingredients, i.e., vegetable oil sterol esters and plant stanol esters. This comparison includes the levels of the major component phytosterols and phytostanols, the levels of minor phytosterol-like components, and the chemical form of the phytosterols and phytostanols (i.e., whether they are esterified). Novartis' GRAS panel finds that the composition of tall oil phytosterols is intermediate between that of vegetable oil sterol esters and plant stanol esters, and notes that the ester forms that are present in vegetable oil sterol esters and plant stanol esters are rapidly de-esterified *in vivo*.

Novartis' GRAS panel also considers that the level of use of tall oil phytosterols in vegetable oil-based spreads is similar to that of the phytosterol and phytostanol components of vegetable oil sterol esters and plant stanol esters. Novartis' GRAS panel further considers that the intended use of tall oil phytosterols as a nutrient in vegetable oil spread to reduce the absorption of cholesterol from the gastrointestinal tract is similar to that of vegetable oil sterol esters and plant stanol esters.

Given the similarities between the composition, level of use, and intended use of tall oil phytosterols compared to that of the related substances, vegetable oil sterol esters and plant stanol esters, Novartis' GRAS Panel concludes that the intended use of tall oil phytosterols does not raise safety questions. In addition, Novartis' GRAS panel asserts that the potential that the use of tall oil phytosterols would have adverse nutritional effects (i.e., on the uptake of fat-soluble vitamins) has been addressed and adequately resolved in the course of the determinations that vegetable oil sterol esters and plant stanol esters are GRAS.

Novartis' GRAS panel concludes that tall oil phytosterols are GRAS, through scientific procedures, when used in vegetable oil-based spreads to help maintain a healthy cholesterol level, provided that the tall oil phytosterols meet the specifications cited in its report and are used in accordance with current good manufacturing practice in an amount not to exceed 12% phytosterol plus phytostanol in the finished product.

Data and information that Novartis describes to support its GRAS determination

Your notice describes a series of studies conducted with free phytosterols, vegetable oil sterol esters, plant stanol esters, or tall oil phytosterols. In general, you rely on published studies conducted with free phytosterols, vegetable oil sterol esters, or plant stanol esters to determine that the major components of tall oil phytosterols are GRAS. To corroborate this determination, you describe unpublished studies conducted with tall oil phytosterols.

Conclusions

Based on the information provided by Novartis, as well as other information available to FDA, the agency has no questions at this time regarding Novartis' conclusion that tall oil phytosterols are GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of tall oil phytosterols. As always, it is the continuing responsibility of Novartis to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review and copying on the Office of Premarket Approval's homepage on the World Wide Web.

Sincerely,
/s/
Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety and Applied Nutrition

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(1)In a submission dated January 11, 1999, Lipton informed FDA of its view that vegetable oil sterol esters are GRAS for use in vegetable oil spreads at levels up to 20% to supplement the nutritive value of the spread, and to help structure the fat phase and reduce the fat and water content of the spread. According to Lipton, the use of vegetable oil sterol esters in vegetable oil-based spreads was intended to help maintain healthy cholesterol levels as part of a diet low in saturated fat and cholesterol.

In a submission dated February 18, 1999, McNeil Consumer Healthcare informed FDA of its view that plant stanol esters are GRAS for use as a nutrient in spread at a level of 1.7 grams of plant stanol esters per serving of spread. According to McNeil, the use of plant stanol esters was intended as a nutrient in food to reduce the absorption of cholesterol from the gastrointestinal tract.

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U. S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Premarket Approval

Agency Response Letter
GRAS Notice No. GRN 000048

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Washington, DC 20204

November 27, 2000

Steven D. McCurry, Ph.D.
Cargill Incorporated
15407 McGinty Road West, MS110
Wayzata, MN, 55391-2399

Re: GRAS Notice No. GRN 000048

Dear Dr. McCurry:

The Food and Drug Administration (FDA) is responding to the notice, dated June 1, 2000, that you submitted in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS)). FDA received the notice on June 2, 2000 and designated it as GRAS Notice No. GRN 000048. In a letter of October 24, 2000, you provided additional clarifying information.

The subject of your notice is vegetable oil phytosterol esters. The notice informs FDA of the view of Cargill Incorporated (Cargill) that vegetable oil phytosterol esters are GRAS, through scientific procedures, for use as an ingredient in vegetable oil spreads, dressings for salads, bars, and yogurt.

The main sterol components of the ingredient vegetable oil phytosterol esters are beta-sitosterol, campesterol, and stigmasterol. These components of vegetable oil phytosterol esters already are present as ingredients in other vegetable oil based spreads, dressings for salads, bars, and yogurt that have a similar intended use. Your notice describes the manufacturing process for vegetable oil phytosterol esters, in which sterols are esterified with vegetable oil fatty acids. The sterols are mostly derived from soy. The fatty acids are derived from soy, canola, sunflower or other vegetable oils. After the esterification reaction, adsorbents are used to remove trace components and color bodies, and the ingredient is subjected to vacuum stripping and filtration. Your notice includes food grade specifications for vegetable oil phytosterol esters, including a specification for lead of less than 0.1 milligrams/kilogram.

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Your notice describes a series of published studies conducted with free phtytosterols, vegetable oil sterol esters, or plant stanol esters. In general, you rely on the similarity of vegetable oil phytosterol esters to the test articles in these published studies to determine that these studies establish the safety of vegetable oil phytosterol esters. Because evaluation that a use of a food ingredient is safe is a time-dependent judgment, you commit to notify the agency if additional relevant information (i.e., changes in exposure, adverse events, or new scientific data) becomes known with respect to the safety of vegetable oil phytosterol esters.

Cargill views the ingredient vegetable oil phytosterol esters as an additional ingredient choice for manufacturers of currently marketed products that contain an enhanced level of phytosterol esters. For this reason, Cargill considers that the marketing of its ingredient would not change the cumulative dietary intake of phytosterol esters compared to what already is marketed.

Your notice includes the findings of a panel of individuals (Cargill's GRAS panel) who evaluated the data and information that are the basis for Cargill's GRAS determination. Cargill considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food. The clarifying information that you provided in your letter of October 24, 2000, included an addendum to the report of this GRAS panel.

In its original report, Cargill's GRAS panel concludes that the composition of vegetable oil phytosterol esters is equivalent to that of another marketed ingredient (i.e., vegetable oil sterol esters, also known as plant sterol esters), which was the subject of a previous submission to FDA.[1] Cargill's GRAS panel reported that FDA had evaluated vegetable oil sterol esters for use in vegetable oil spreads, dressings for salads, bars, and yogurt. However, as you discussed by telephone in July, 2000, with Dr. Linda Kahl of the Office of Premarket Approval, FDA's evaluation of the intended use of vegetable oil sterol esters was limited to its use in vegetable oil spreads (Ref. 1). FDA's evaluation of the intended use of two related ingredients (i.e., plant stanol esters and tall oil phytosterols)[2] likewise was limited to their use in spreads (Refs. 2 and 3). Thus, at the time that you submitted your GRAS notice, FDA had only evaluated dietary exposure to plant sterol and stanol esters from their consumption in spread. This consumption would be approximately 3 grams of plant sterols or plant stanols per person per day (which is equivalent to approximately 5 grams of plant sterol esters or plant stanol esters per person per day). At that time, FDA had not evaluated the implications, if any, of the cumulative dietary exposure to plant sterol esters or plant stanol esters as a result of their use in food products such as dressings for salads, bars, and yogurt.

Your October 24 letter acknowledges that FDA's previous evaluation of the use of plant sterols and stanols, in free or esterified form, was limited to the use of these ingredients in spreads. Your October 24 letter also discusses an interim final rule that FDA issued, after FDA received your notice, to authorize a health claim for plant sterol/stanol esters (65 FR 54685; September 8, 2000). FDA authorized this health claim for plant sterol esters when used in spreads and dressings for salads, and for plant stanol esters when used in spreads, dressings for salads, and snack bars. In this interim final rule, FDA acknowledged receipt and consideration of information regarding the use of plant sterol esters and plant stanol esters in a broader array of food categories than spread. FDA also concluded that the health claim petitioners had met the burden to demonstrate, to FDA's satisfaction, that the use of plant sterol esters and plant stanol esters in this broader array of food categories is safe and lawful. In your view, the interim final rule makes clear that the primary source of data and information that FDA relied on in reaching this conclusion was the data and information that FDA evaluated regarding the use of these ingredients in spreads. Likewise, Cargill's GRAS panel primarily relied on data and information that supported the use of these ingredients in spreads. Thus, it is Cargill's view that the original report of its GRAS panel is consistent with the views expressed by FDA in the interim final rule authorizing a health claim.

Based on the information provided by Cargill, as well as other information available to FDA, the agency has no questions at this time regarding Cargill's conclusion that vegetable oil phytosterol esters are GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of vegetable oil phytosterol esters. As always, it is the continuing responsibility of Cargill to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review and copying on the Office of Premarket Approval's homepage on the Internet (at http://www.cfsan.fda.gov/~lrd/foodadd.html).

Sincerely,
/s/
Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety and Applied Nutrition

References

1. Letter dated April 30, 1999, from Alan Rulis of FDA to Daniel R. Dwyer.

2. Letter dated May 17, 1999, from Alan Rulis of FDA to Vivian A. Chester and Edward B. Nelson.

3. Letter dated April 24, 2000, from Alan Rulis of FDA to Judith A. Weinstein.

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(1)In a submission dated January 11, 1999, Lipton informed FDA of its view that vegetable oil sterol esters are GRAS for use in spreads at a level up to 20 per cent.

(2)In a submission dated February 18, 1999, McNeil Consumer Healthcare informed FDA of its view that plant stanol esters are GRAS for use in spreads at a level of 1.7 grams of plant stanol esters per serving of spread. In a GRAS Notice dated January 28, 2000 (GRN No. 000039), Novartis Consumer Health, Inc. informed FDA of its view that tall oil phytosterols are GRAS for use in spreads at a level of up to 12 percent.

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U. S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Premarket Approval

Agency Response Letter
GRAS Notice No. GRN 000053

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Washington, DC 20204

December 20, 2000

Maury M. Bandurraga, Ph.D.
The Procter & Gamble Company
Winton Hill Technical Center
6071 Center Hill Avenue
Cincinnati, OH 45224

Re: GRAS Notice No. GRN 000053

Dear Dr. Bandurraga:

The Food and Drug Administration (FDA) is responding to the notice, dated July 17, 2000, that you submitted in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS)). FDA received the notice on July 24, 2000 and designated it as GRAS Notice No. GRN 000053.

The subject of your notice is phytosterol esters. The notice informs FDA of the view of The Procter & Gamble Company (P&G) that phytosterol esters are GRAS, through scientific procedures, for use as an ingredient in vegetable oil, at a level up to 13.3 per cent by weight, for home use applications such as baking, frying, and salad dressings.

You obtain the phytosterol esters from Cargill, who submitted a GRAS notice for its ingredient in June, 2000 (GRN 000048). Your notice describes the identity and composition of the ingredient produced by Cargill. Your notice includes food grade specifications for phytosterol esters, including a specification for lead of less than 0.1 milligrams/kilogram.

The major components of phytosterol esters are beta-sitosterol, campesterol, and stigmasterol. These components already are present in currently marketed ingredients. These products include "vegetable oil sterol esters," which are marketed by Lipton in Take Control™ brand spread, "plant stanol esters," which are marketed by McNeil Consumer Healthcare in Benecol™ brand spread, and "tall oil

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phytosterols" which are marketed by Novartis Consumer Health, Inc. in Phytrol™ brand spread. FDA had previously evaluated these ingredients when consumed in spread (Refs. 1 through 3). Consumption would be approximately 3 grams of plant sterols or plant stanols per person per day (which is equivalent to approximately 5 grams of plant sterol esters or plant stanol esters per person per day) when following specific label directions recommending consumption of multiple servings per day of the spread. You estimate that the expected additional consumption of phytosterol esters, at the 90th percentile level, from your proposed use in vegetable oil would range from approximately 750 milligrams per person per day to approximately 2100 milligrams per person per day.

Your notice describes an unpublished study demonstrating the stability of phytosterols during typical home cooking conditions. You conclude that no significant new oxidized species were formed by heating the vegetable oil containing phytosterol esters compared to standard vegetable oil. Your notice also describes a series of published studies conducted with free phytosterol, vegetable oil sterol esters, plant stanol esters, or tall oil phytosterols. Because evaluation that a use of a food ingredient is safe is a time-dependent judgment, you mention that P&G plans, as for any new product, to conduct the firm's usual post-market evaluation of consumer acceptance and use for this new product and to share with FDA any information on product usage and exposure that materially changes the GRAS determination presented in your notice.

Your notice includes the findings of a panel of individuals (P&G's GRAS panel) who evaluated the data and information that are the basis for P&G's GRAS determination. P&G considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food. In its report, P&G's GRAS panel concludes that the composition of the ingredient that P&G would add to vegetable oil is equivalent to the ingredient "vegetable oil sterol esters" that is marketed by Lipton in its Take Control™ brand of vegetable spread. In its report, P&G's GRAS panel considered additional phytosterol intake from the consumption of P&G's vegetable oil product compared to the consumption of phytosterol esters contained in currently available spreads and assessed phytosterol stability during typical home cooking conditions.

Based on the information provided by P&G, as well as other information available to FDA, the agency has no questions at this time regarding P&G's conclusion that phytosterol esters are GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of phytosterol esters. As always, it is P&G's continuing responsibility to ensure that food ingredients that P&G markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review and copying on the Office of Premarket Approval's homepage on the Internet (at http://vm.cfsan.fda.gov/~lrd/foodadd.html).

Sincerely,
/s/
Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety and Applied Nutrition

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References

1. Letter dated April 30, 1999, from Alan Rulis of FDA to Daniel R. Dwyer.
2. Letter dated May 17, 1999, from Alan Rulis of FDA to Vivian A. Chester and Edward B. Nelson.
3. Letter dated April 24, 2000, from Alan Rulis of FDA to Judith A. Weinstein.

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U. S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Premarket Approval

Agency Response Letter
GRAS Notice No. GRN 000061

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Washington, DC 20204

April 18, 2001

Mark W. Empie, Ph.D.
Vice President Regulatory and Scientific Affairs
Archer Daniels Midland Company
1001 North Brush College Road
Decatur, IL 62521

Re: GRAS Notice No. GRN 000061

Dear Dr. Empie:

The Food and Drug Administration (FDA) is responding to the notice, dated November 22, 2000, that you submitted on behalf of Archer Daniels Midland (ADM) in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS)). FDA received the notice on November 27, 2000 and designated it as GRAS Notice No. GRN 000061. In a letter of February 28, 2001, you provided additional clarifying information.

The subjects of the notice are plant sterols and plant sterol esters. The notice informs FDA of the view of ADM that plant sterols are GRAS, through scientific procedures, for use as an ingredient[(1)] in vegetable oil spreads, dressings for salad, health drinks, health bars, and yogurt-type products at a level of 1 gram per serving, and as a raw material in the manufacture of plant sterol esters for use as an ingredient in the same foods at a level of 1.65 grams (i.e., 1 gram sterol equivalent) per serving. Because evaluation that a use of a food ingredient is safe is a time-dependent judgment, ADM commits to provide production and sale data, for the purpose of monitoring usage of plant sterols and plant sterol esters, if FDA requests such data in the future.

The main sterol components of the ingredients plant sterols and plant sterol esters are beta-sitosterol, campesterol, and stigmasterol. ADM describes the manufacturing processes for plant sterols and plant sterol esters, in which the plant sterols are esterified with vegetable oil fatty acids. The sterols are derived from oil seeds such as corn, palm, soy, rape and sunflower. The fatty acids are preferentially

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derived from soy, sunflower, safflower, and canola; but corn, peanut, cottonseed and palm may also be used as sources. ADM's notice includes food grade specifications for plant sterols and plant sterol esters, including a specification for lead of less than 0.1 parts per million.

ADM intends to provide to its customers plant sterols and plant sterol esters for incorporation into spreads, dressings for salad, yogurt-type products, health drinks, and health bars. ADM estimates that a total daily consumption of plant sterols for an individual who would consume all the listed products and conventional food sources of plant sterols (i.e., 0.25 grams of phytosterols per day) would be up to 5.5 grams at the mean level and up to 10.6 grams at the 90th percentile level.

ADM considers that the ingredients plant sterols and plant sterol esters are similar to the ingredient vegetable oil sterol esters, which is marketed by Lipton and which FDA previously evaluated for use in vegetable oil based spreads (Ref. 1). In ADM's view, Lipton's submission of January 11, 1999, presents a thorough evaluation of the available literature. This literature was evaluated by a panel of individuals (Lipton's GRAS panel) whom Lipton considered qualified by scientific training and experience to evaluate the safety of substances added to food. ADM notes that several relevant studies that were not publicly available at the time of Lipton's submission have now been published. Because the publicly available information draws on studies that included both sterol esters and free sterols, ADM concludes that this literature supports the safety of both of its ingredients.[2]

ADM notes that Lipton's GRAS panel set an acceptable daily intake (ADI) for vegetable oil sterol esters of 130 milligrams/kilogram/day (as the free phytosterol), equivalent to 9.1 grams per day for a 70 kg person. ADM discusses the rationale that Lipton's GRAS panel used to set this ADI.

ADM notes that its own estimated daily intake (i.e., 10.6 grams per day at the 90th percentile level) exceeds the ADI set by Lipton's GRAS panel by 16 percent. ADM discusses the rationale for its own conclusion that dietary exposure to plant sterols and plant sterol esters from ADM's proposed uses remains within a safe range. To a large extent, ADM relies on consumers' previous exposure to a drug product (i.e., *Cytellin*) marketed by Eli Lilly as a treatment for hypercholesterolemia during the 1950's to 1980's. The primary component of *Cytellin* (beta-sitosterol) was the same as the primary component of plant sterols. More than 1800 people participated in clinical studies conducted with *Cytellin* to assess effects on blood cholesterol levels, with no reported adverse effects. Individuals who used the marketed drug typically consumed dosages ranging from 9 to 30 grams per day. More recently, plant sterols as the esters have been the subject of additional studies and there has been general consumption in the United States. For all of these reasons, ADM considers that the ADI set by Lipton's GRAS panel is a conservative number.

Based on the information provided by ADM, as well as other information available to FDA, the agency has no questions at this time regarding ADM's conclusion that the ingredients plant sterols and plant sterol esters are GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of plant sterols or plant sterols esters. As always, it is the continuing responsibility of ADM to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review and copying on the Office of Premarket Approval's homepage on the Internet (at http://www.cfsan.fda.gov/~lrd/foodadd.html).

Sincerely,

000067

/s/
Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety and Applied Nutrition

References

1. Letter dated April 30, 1999, from Alan Rulis of FDA to Daniel R. Dwyer.

2. Letter dated May 17, 1999, from Alan Rulis of FDA to Vivian A. Chester and Edward B. Nelson.

3. Letter dated April 24, 2000, from Alan Rulis of FDA to Judith A. Weinstein.

4. Letter dated November 27, 2000, from Alan Rulis of FDA to Steven D. McCurry.

5. Letter dated December 20, 2000, from Alan Rulis of FDA to Maury M. Bandurraga.

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(1)In describing the intended use of plant sterols and plant sterol esters, ADM asserts that plant sterols contribute nutritive value. ADM's assertion raises an issue under section 403(r) of the Federal Food, Drug, and Cosmetic Act, which lays out the statutory framework for a health claim. Under 21 CFR 101.14(b)(3)(i), the substance that is the subject of a health claim must contribute taste, aroma, or nutritive value, or any other technical effect listed in 21 CFR 170.3(o), to the food and must retain that attribute when consumed at the levels that are necessary to justify a claim. Whether plant sterols and plant sterol esters contribute nutritive value within the meaning of 21 CFR 101.14(b)(3)(i) is the purview of the Office of Nutritional Products, Labeling, and Dietary Supplements (ONPLDS) in FDA's Center for Food Safety and Applied Nutrition. The Office of Premarket Approval neither consulted with ONPLDS on this labeling issue nor evaluated the information in ADM's notice to determine whether it would support ADM's view that plant sterols and plant sterol esters contribute nutritive value.

(2)FDA has evaluated the data and information supporting the safety of similar ingredients when consumed in vegetable oil based spread and additional product categories, including dressings for salads, bars, yogurt, or vegetable oils for home use applications such as baking, frying, and salad dressings (Refs. 2-5).

Content last updated by lsk on 2001-APR-24
Hypertext last updated by lsk on 2001-APR-24

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
February 4, 2003

Agency Response Letter
GRAS Notice No. GRN 000112

C. K. Gund, Ph.D.
Phoenix Regulatory Associates
21525 Ridgetop Circle, Suite 240
Sterling, VA 20166

Re: GRAS Notice No. GRN 000112

Dear Dr. Gund:

The Food and Drug Administration (FDA) is responding to the notice, dated August 15, 2002, that you submitted on behalf of Teriaka Ltd. (Teriaka) in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received the notice on August 19, 2002, filed it on August 19, 2002, and designated it as GRAS Notice No. GRN 000112.

The subject of the notice is phytosterols. The phytosterols would be added to food as a component of a fatty mixture (either a vegetable fat mixture, a vegetable oil mixture, or an anhydrous milk fat mixture). The notice informs FDA of the view of Teriaka that phytosterols are GRAS, through scientific procedures, for use as an ingredient in margarine and vegetable-based spreads (margarine-like); yogurt and yogurt-like products; milk-based juice beverages; ice cream and non-standardized ice cream products; cream cheese and cream cheese-like products; snack bars (health bars); salad dressing, mayonnaise, French dressing, and dressings for salads; and white breads, white rolls and buns, and comparable non-standardized white bread products.

Teriaka describes the products it manufactures containing phytosterols as vegetable fat mixtures with phytosterols, vegetable oil mixtures with phytosterols, or anhydrous milk fat mixtures with phytosterols, depending on the fat used to produce the sterol-enriched ingredient. The phytosterols that Teriaka uses are either from vegetable oils (soybean, cottonseed, corn, sunflower seed, canola, or peanut) or tall oil extracted from pine trees (*Pinus pinaster* and *Pinus syvestris*). Teriaka notes that the vegetable oil phytosterols that it processes into a fatty mixture are the subject of a previous GRAS notice, i.e., GRN 000061. Teriaka notes that the tall oil phytosterols that it processes into a fatty mixture predominantly contain beta-sitosterol, beta-sitostanol, campesterol, and campestanol and compares the composition of these tall oil phytosterols with that of the tall oil phytosterols that are the subject of a previous GRAS notice, i.e., GRN 000039.

Teriaka describes the manufacture of the tall oil phytosterols that it processes into a fatty mixture. Phytosterols are produced from raw tall oil pitch, which is produced from pine trees as a by-product of the kraft pulping process and is composed of the neutral non-lignin, non-cellulosic portion of the pine

trees. The raw tall oil pitch is distilled to give fatty acids, rosin acids, and tall oil pitch. The tall oil pitch is then extracted with alcohol and heated to give primary phytosterol crystals. After cooling, these crystals are washed with water and filtered to separate them from the tall oil residues. The phytosterols are recrystallized, filtered, dried under vacuum, and then milled and sieved to obtain the required crystal size. Teriaka provides specifications for the tall oil phytosterols and for the fatty mixtures that contain phytosterols. Teriaka estimates that per capita intake of phytosterols from use in fatty mixtures would be 1.6 grams per person per day (g/p/d) at the mean and 3.6 g/p/d at the 90th percentile.[1]

In its notice, Teriaka discusses published studies addressing the safety of acute, sub-chronic, and chronic intakes of phytosterols and the potential for genotoxic, reproductive, or developmental effects of phytosterols. Teriaka also discusses published studies addressing the metabolism of plant sterols in animals, the effect of phytosterols on sex hormones in animals and humans, the effect of phytosterols on fat soluble vitamins and carotenoids, and the safety of the cumulative intake of plant sterols. Teriaka notes that most of these studies were discussed in previous GRAS notices and Food Master Files submitted to FDA by other manufacturers (i.e., GRN 000039, GRN 000048, GRN 000053, GRN 000061, FMF 000625, and FMF 000626). Teriaka concludes that its ingredients containing either vegetable or tall oil phytosterols are safe for their intended use.

Based on the information provided by Teriaka, as well as other information available to FDA, the agency has no questions at this time regarding Teriaka's conclusion that phytosterols added as a component of a fatty mixture are GRAS under the conditions of their intended use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of phytosterols. As always, it is the continuing responsibility of Teriaka to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In the notice, Teriaka states its intention to use phytosterols in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity. If you have any questions about the use of phytosterols in standardized foods that would be marketed in the United States, you should contact the staff in Office of Nutritional Products, Labeling, and Dietary Supplements (ONPLDS), Division of Standards and Labeling Regulations, HFS-820, 5100 Paint Branch Parkway, College Park, MD 20740. You can reach this division by telephone at (301) 436-2375. The Office of Food Additive Safety (OFAS) neither consulted with ONPLDS on the use of phytosterols in standardized foods nor evaluated the information in your notice to determine whether your use of phytosterols is permitted by the applicable standards of identity.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review and copying on the homepage of the Office of Food Additive Safety (on the Internet at http://www.cfsan.fda.gov/~lrd/foodadd.html).

Sincerely,
/s/
Alan M. Rulis, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

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(1)FDA normally considers exposure to an ingredient only for eaters of foods containing the ingredient. For these phytosterols, the per capita intake estimated by Teriaka is comparable to the "eaters only" intake estimated by FDA.

Food Ingredients and Packaging | Summary of all GRAS Notices

Foods Home | FDA Home | Search/Subject Index | Disclaimers & Privacy Policy | Accessibility/Help

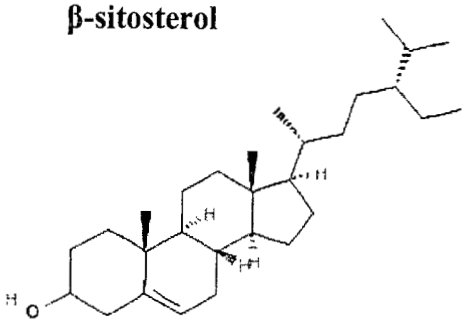
Content last updated by amd/pmg on 2002-MAR-12
Hypertext updated by amd/rxm/pmg on 2002-MAR-19

Appendix B

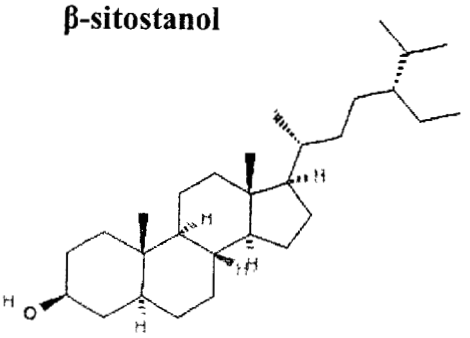
Appendix B

Structural Formulas of Main Wood Sterol Components

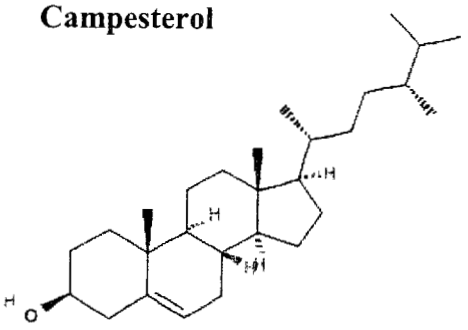
β-sitosterol



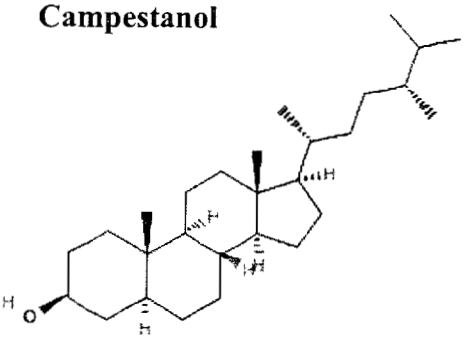
β-sitostanol



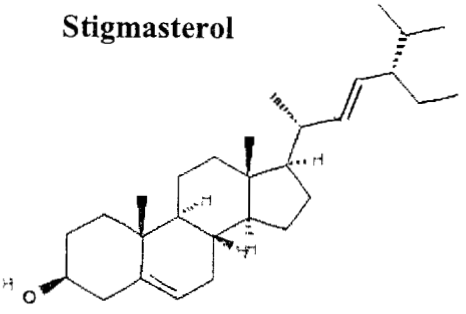
Campesterol



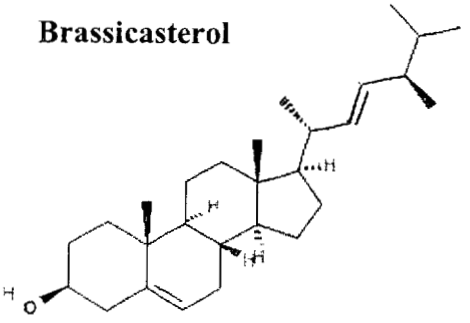
Campestanol



Stigmasterol



Brassicasterol



Appendix C

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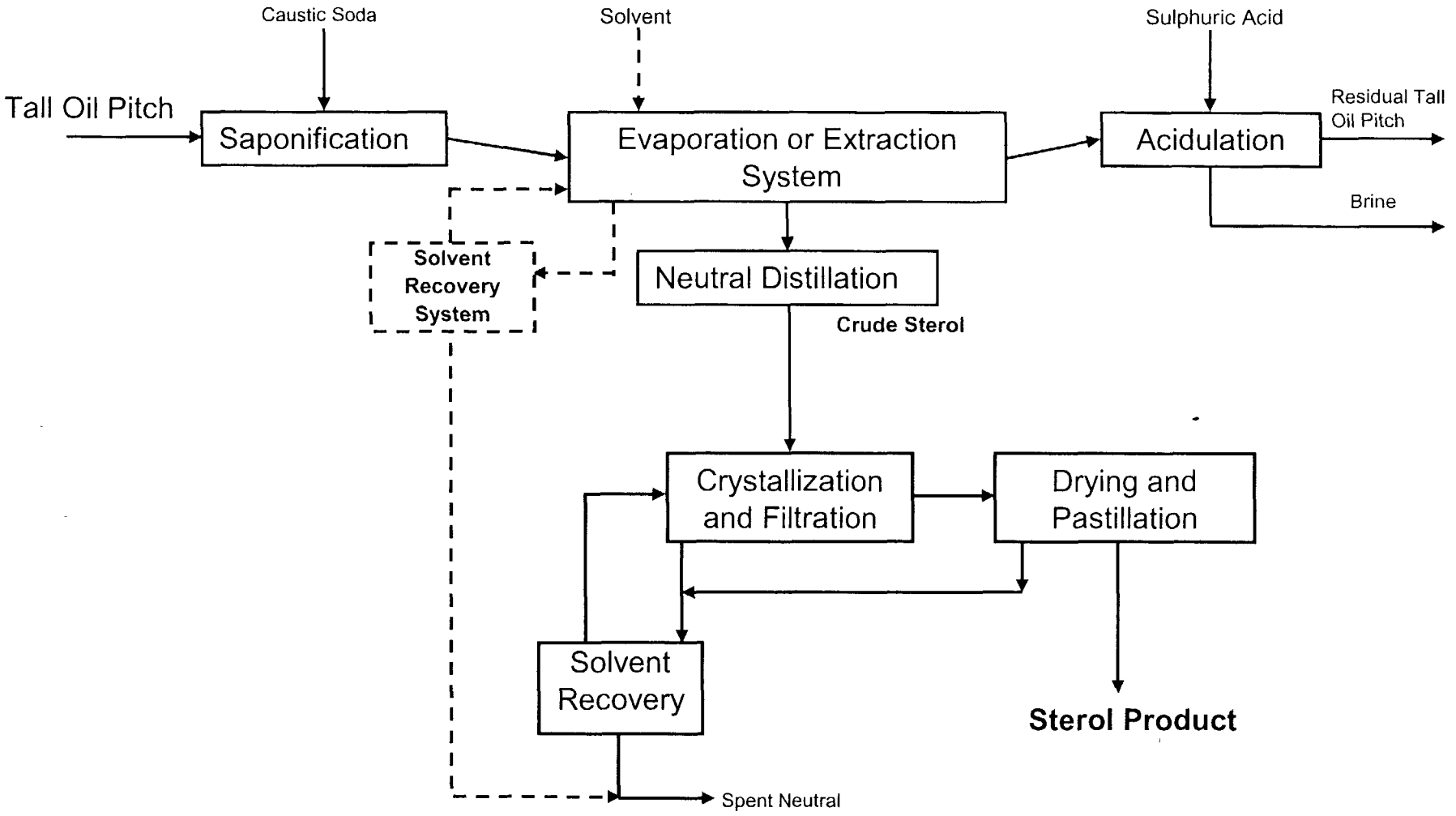
Appendix C

Manufacturing Flow Diagram of Wood Sterols

Sterol Process Flow Diagram



Appendix D

Appendix D

Analyses of Pesticide Residues in Wood Sterols

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Certificate of Analysis

Marcia Croce
ADM James R. Randall Research Centre
1001 N. Brush College Road
Decatur
IL 62521
USA

Report No: P5-01538
Purchase Order: None Supplied
Date Received: 14th February 2005
Date Started: 3rd March 2005

Pesticide Screening

RSSL Code: **P5-01538-1** Description: Wood Sterols
Your Refs: WSP 1004004

Results of Pesticides

The following tests were subcontracted to UKAS accredited laboratory no 1668

Method	Analysis	Result	Units
	Aldrin	<0.020	mg/kg
	Chlordane	<0.020	mg/kg
	DDT (Total Isomers)	<0.020	mg/kg
	Dieldrin	<0.020	mg/kg
	Endosulphan	<0.020	mg/kg
	Endosulphan Sulphate	<0.020	mg/kg
	Endrin	<0.020	mg/kg
	HCB	<0.020	mg/kg
	Alpha HCH	<0.020	mg/kg
	Beta HCH	<0.020	mg/kg
	Gamma HCH (lindane)	<0.020	mg/kg
	Heptachlor	<0.020	mg/kg
	Heptachlor Epoxide	<0.020	mg/kg
	Tecnazene	<0.020	mg/kg
	Permethrin	<0.020	mg/kg
	Deltamethrin	<0.020	mg/kg
	Fenvalerate	<0.020	mg/kg
	Cyfluthrin	<0.020	mg/kg
	Cypermethrin	<0.020	mg/kg

Approved By: Simon Flanagan
Head of Routine Analysis

(b) [redacted]

Date: 3rd March 2005

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Fax (Int: +44 118 9868932) 0118 9868932
e-mail enquiries@rssl.com web www.rssl.com

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ADM James R. Randall Research Centre		Purchase Order:	None Supplied
1001 N. Brush College Road		Date Received:	14th February 2005
Decatur		Date Started:	3rd March 2005
IL 62521			
USA			Page 2 of 12

Pesticide Screening

RSSL Code: **P5-01538-1** Description: Wood Sterols

Your Refs: WSP 1004004

Results of Pesticides (Continued)

Method	Analysis	Result	Units
The following tests were subcontracted to UKAS accredited laboratory no 1668			
	Cyhalothrin	<0.020	mg/kg
	Acephate	<0.020	mg/kg
	Azinphos ethyl	<0.020	mg/kg
	Azinphos methyl	<0.020	mg/kg
	Bromophos	<0.020	mg/kg
	Bromophos-ethyl	<0.020	mg/kg
	Carbophenthion	<0.020	mg/kg
	Chlorpyriphos	<0.020	mg/kg
	Chlorpyriphos-Methyl	<0.020	mg/kg
	Chlorfenvinphos	<0.020	mg/kg
	Coumaphos*	<0.020	mg/kg
	Diazinon	<0.020	mg/kg
	Dichlofenthion	<0.020	mg/kg
	Dichlorvos	<0.020	mg/kg
	Dicrotophos	<0.020	mg/kg
	Dimethoate	<0.020	mg/kg
	Ethion	<0.020	mg/kg
	Ethoprophos	<0.020	mg/kg
	Etrimphos	<0.020	mg/kg

Approved By: Simon Flanagan (b) [redacted] Date: 3rd March 2005

Head of Routine Analysis

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Decatur		Date Started:	3rd March 2005
IL 62521			
USA			Page 3 of 12

Pesticide Screening

RSSL Code: **P5-01538-1** Description: Wood Sterols

Your Refs: WSP 1004004

Results of Pesticides (Continued)

Method	Analysis	Result	Units
The following tests were subcontracted to UKAS accredited laboratory no 1668			
	Fenamiphos	<0.020	mg/kg
	Fenchlorfos	<0.020	mg/kg
	Fenitrothion	<0.020	mg/kg
	Fenthion	<0.020	mg/kg
	Fonophos	<0.020	mg/kg
	Malathion*	<0.020	mg/kg
	Methacriphos	<0.020	mg/kg
	Methadithion	<0.020	mg/kg
	Methamidophos	<0.020	mg/kg
	Mevinphos	<0.020	mg/kg
	Omethoate	<0.020	mg/kg
	Parathion	<0.020	mg/kg
	Parathion-methyl	<0.020	mg/kg
	Phorate*	<0.020	mg/kg
	Phosalone	<0.020	mg/kg
	Phosmet	<0.020	mg/kg
	Pirimiphos-Methyl	<0.020	mg/kg
	Propetamphos	<0.020	mg/kg
	Quinalphos	<0.020	mg/kg

Approved By: Simon Flanagan (b) [redacted] Date: 3rd March 2005

Head of Routine Analysis

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ADM James R. Randall Research Centre		Purchase Order:	None Supplied
1001 N. Brush College Road		Date Received:	14th February 2005
Decatur		Date Started:	3rd March 2005
IL 62521			
USA			Page 4 of 12

Pesticide Screening

RSSL Code: **P5-01538-1** Description: Wood Sterols

Your Refs: WSP 1004004

Results of Pesticides (Continued)

Method	Analysis	Result	Units
The following tests were subcontracted to UKAS accredited laboratory no 1668			
	Tetrachlorvinfos	<0.020	mg/kg
	Turbufos*	<0.020	mg/kg
	Vinclozolin*	<0.020	mg/kg
	Fluemetralin	<0.020	mg/kg
	Iprodione	<0.020	mg/kg

Approved By: Simon Flanagan
Head of Routine Analysis

(b) [redacted]

Date: 3rd March 2005

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1001 N. Brush College Road		Date Received:	14th February 2005
Decatur		Date Started:	3rd March 2005
IL 62521			
USA			Page 5 of 12

Pesticide Screening

RSSL Code: **P5-01538-2** Description: Wood Sterols

Your Refs: WSP 1104005

Results of Pesticides

Method	Analysis	Result	Units
The following tests were subcontracted to UKAS accredited laboratory no 1668			
	Aldrin	<0.020	mg/kg
	Chlordane	<0.020	mg/kg
	DDT (Total Isomers)	<0.020	mg/kg
	Dieldrin	<0.020	mg/kg
	Endosulphan	<0.020	mg/kg
	Endosulphan Sulphate	<0.020	mg/kg
	Endrin	<0.020	mg/kg
	HCB	<0.020	mg/kg
	Alpha HCH	<0.020	mg/kg
	Beta HCH	<0.020	mg/kg
	Gamma HCH (lindane)	<0.020	mg/kg
	Heptachlor	<0.020	mg/kg
	Heptachlor Epoxide	<0.020	mg/kg
	Tecnazene	<0.020	mg/kg
	Permethrin	<0.020	mg/kg
	Deltamethrin	<0.020	mg/kg
	Fenvalerate	<0.020	mg/kg
	Cyfluthrin	<0.020	mg/kg
	Cypermethrin	<0.020	mg/kg

Approved By: Simon Flanagan (b) [redacted] Date: 3rd March 2005

Head of Routine Analysis

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ADM James R. Randall Research Centre		Purchase Order:	None Supplied
1001 N. Brush College Road		Date Received:	14th February 2005
Decatur		Date Started:	3rd March 2005
IL 62521			
USA			Page 6 of 12

Pesticide Screening

RSSL Code: **P5-01538-2** Description: Wood Sterols

Your Refs: WSP 1104005

Results of Pesticides (Continued)

Method	Analysis	Result	Units
The following tests were subcontracted to UKAS accredited laboratory no 1668			
	Cyhalothrin	<0.020	mg/kg
	Acephate	<0.020	mg/kg
	Azinphos ethyl	<0.020	mg/kg
	Azinphos methyl	<0.020	mg/kg
	Bromophos	<0.020	mg/kg
	Bromophos-ethyl	<0.020	mg/kg
	Carbophenthion	<0.020	mg/kg
	Chlorpyriphos	<0.020	mg/kg
	Chlorpyriphos-Methyl	<0.020	mg/kg
	Chlorfenvinphos	<0.020	mg/kg
	Coumaphos*	<0.020	mg/kg
	Diazinon	<0.020	mg/kg
	Dichlofenthion	<0.020	mg/kg
	Dichlorvos	<0.020	mg/kg
	Dicrotophos	<0.020	mg/kg
	Dimethoate	<0.020	mg/kg
	Ethion	<0.020	mg/kg
	Ethoprophos	<0.020	mg/kg
	Etrimphos	<0.020	mg/kg

Approved By: Simon Flanagan (b) [redacted] Date: 3rd March 2005

Head of Routine Analysis

These results relate only to the sample(s) tested and do not guarantee the bulk of the material to be of equal quality. This report shall not be reproduced except in full without the written approval of RSSL. RSSL staff were not responsible for sampling and cannot be held liable in respect of the use to which this information is put.

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ADM James R. Randall Research Centre		Purchase Order:	None Supplied
1001 N. Brush College Road		Date Received:	14th February 2005
Decatur		Date Started:	3rd March 2005
IL 62521			
USA			Page 7 of 12

Pesticide Screening

RSSL Code: **P5-01538-2** Description: Wood Sterols

Your Refs: WSP 1104005

Results of Pesticides (Continued)

Method	Analysis	Result	Units
The following tests were subcontracted to UKAS accredited laboratory no 1668			
	Fenamiphos	<0.020	mg/kg
	Fenchlorfos	<0.020	mg/kg
	Fenitrothion	<0.020	mg/kg
	Fenthion	<0.020	mg/kg
	Fonophos	<0.020	mg/kg
	Malathion*	<0.020	mg/kg
	Methacriphos	<0.020	mg/kg
	Methadithion	<0.020	mg/kg
	Methamidophos	<0.020	mg/kg
	Mevinphos	<0.020	mg/kg
	Omethoate	<0.020	mg/kg
	Parathion	<0.020	mg/kg
	Parathion-methyl	<0.020	mg/kg
	Phorate*	<0.020	mg/kg
	Phosalone	<0.020	mg/kg
	Phosmet	<0.020	mg/kg
	Pirimiphos-Methyl	<0.020	mg/kg
	Propetamphos	<0.020	mg/kg
	Quinalphos	<0.020	mg/kg

Approved By: Simon Flanagan
Head of Routine Analysis

(b) [redacted]

Date: 3rd March 2005

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Certificate of Analysis

Marcia Croce		Report No:	P5-01538
ADM James R. Randall Research Centre		Purchase Order:	None Supplied
1001 N. Brush College Road		Date Received:	14th February 2005
Decatur		Date Started:	3rd March 2005
IL 62521			
USA			Page 8 of 12

Pesticide Screening

RSSL Code: **P5-01538-2** Description: Wood Sterols

Your Refs: WSP 1104005

Results of Pesticides (Continued)

Method	Analysis	Result	Units
The following tests were subcontracted to UKAS accredited laboratory no 1668			
	Tetrachlorvinfos	<0.020	mg/kg
	Turbufos*	<0.020	mg/kg
	Vinclozolin*	<0.020	mg/kg
	Fluemetralin	<0.020	mg/kg
	Iprodione	<0.020	mg/kg

Approved By: Simon Flanagan (b) [redacted] Date: 3rd March 2005

Head of Routine Analysis

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1001 N. Brush College Road
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USA

Report No: P5-01538
Purchase Order: None Supplied
Date Received: 14th February 2005
Date Started: 3rd March 2005

Pesticide Screening

RSSL Code: **P5-01538-3** Description: Wood Sterols
Your Refs: WSP 1104006

Results of Pesticides

The following tests were subcontracted to UKAS accredited laboratory no 1668

Method	Analysis	Result	Units
	Aldrin	<0.020	mg/kg
	Chlordane	<0.020	mg/kg
	DDT (Total Isomers)	<0.020	mg/kg
	Dieldrin	<0.020	mg/kg
	Endosulphan	<0.020	mg/kg
	Endosulphan Sulphate	<0.020	mg/kg
	Endrin	<0.020	mg/kg
	HCB	<0.020	mg/kg
	Alpha HCH	<0.020	mg/kg
	Beta HCH	<0.020	mg/kg
	Gamma HCH (lindane)	<0.020	mg/kg
	Heptachlor	<0.020	mg/kg
	Heptachlor Epoxide	<0.020	mg/kg
	Tecnazene	<0.020	mg/kg
	Permethrin	<0.020	mg/kg
	Deltamethrin	<0.020	mg/kg
	Fenvalerate	<0.020	mg/kg
	Cyfluthrin	<0.020	mg/kg
	Cypermethrin	<0.020	mg/kg

Approved By: Simon Flanagan
Head of Routine Analysis

(b) [redacted]

Date: 3rd March 2005

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Decatur	Date Started: 3rd March 2005
IL 62521	
USA	Page 10 of 12

Pesticide Screening

RSSL Code: **P5-01538-3** Description: Wood Sterols

Your Refs: WSP 1104006

Results of Pesticides (Continued)

Method	Analysis	Result	Units
The following tests were subcontracted to UKAS accredited laboratory no 1668			
	Cyhalothrin	<0.020	mg/kg
	Acephate	<0.020	mg/kg
	Azinphos ethyl	<0.020	mg/kg
	Azinphos methyl	<0.020	mg/kg
	Bromophos	<0.020	mg/kg
	Bromophos-ethyl	<0.020	mg/kg
	Carbophenthion	<0.020	mg/kg
	Chlorpyriphos	<0.020	mg/kg
	Chlorpyriphos-Methyl	<0.020	mg/kg
	Chlorfenvinphos	<0.020	mg/kg
	Coumaphos*	<0.020	mg/kg
	Diazinon	<0.020	mg/kg
	Dichlofenthion	<0.020	mg/kg
	Dichlorvos	<0.020	mg/kg
	Dicrotophos	<0.020	mg/kg
	Dimethoate	<0.020	mg/kg
	Ethion	<0.020	mg/kg
	Ethoprophos	<0.020	mg/kg
	Etrimphos	<0.020	mg/kg

Approved By: Simon Flanagan (b) [redacted] Date: 3rd March 2005

Head of Routine Analysis

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ADM James R. Randall Research Centre		Purchase Order:	None Supplied
1001 N. Brush College Road		Date Received:	14th February 2005
Decatur		Date Started:	3rd March 2005
IL 62521			
USA			Page 11 of 12

Pesticide Screening

RSSL Code: **P5-01538-3** Description: Wood Sterols

Your Refs: WSP 1104006

Results of Pesticides (Continued)

Method	Analysis	Result	Units
The following tests were subcontracted to UKAS accredited laboratory no 1668			
	Fenamiphos	<0.020	mg/kg
	Fenchlorfos	<0.020	mg/kg
	Fenitrothion	<0.020	mg/kg
	Fenthion	<0.020	mg/kg
	Fonophos	<0.020	mg/kg
	Malathion*	<0.020	mg/kg
	Methacriphos	<0.020	mg/kg
	Methadithion	<0.020	mg/kg
	Methamidophos	<0.020	mg/kg
	Mevinphos	<0.020	mg/kg
	Omethoate	<0.020	mg/kg
	Parathion	<0.020	mg/kg
	Parathion-methyl	<0.020	mg/kg
	Phorate*	<0.020	mg/kg
	Phosalone	<0.020	mg/kg
	Phosmet	<0.020	mg/kg
	Pirimiphos-Methyl	<0.020	mg/kg
	Propetamphos	<0.020	mg/kg
	Quinalphos	<0.020	mg/kg

Approved By: Simon Flanagan
Head of Routine Analysis

(b)

Date: 3rd March 2005

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ADM James R. Randall Research Centre
1001 N. Brush College Road
Decatur
IL 62521
USA

Report No: P5-01538
Purchase Order: None Supplied
Date Received: 14th February 2005
Date Started: 3rd March 2005

Pesticide Screening

RSSL Code: **P5-01538-3** Description: Wood Sterols

Your Refs: WSP 1104006

Results of Pesticides (Continued)

Method	Analysis	Result	Units
The following tests were subcontracted to UKAS accredited laboratory no 1668			
	Tetrachlorvinfos	<0.020	mg/kg
	Turbufos*	<0.020	mg/kg
	Vinclozolin*	<0.020	mg/kg
	Fluemetralin	<0.020	mg/kg
	Iprodione	<0.020	mg/kg

Approved By: Simon Flanagan
Head of Routine Analysis

(b) [redacted]

Date: 3rd March 2005

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Appendix E

000088.001

Appendix E

Dioxin Analyses of Wood Sterols

Certificate of Analysis

Contact.	MICHELLE JONES	Report No	P5-01277B re-issue
Company:	ADM NATURAL HEALTH & NUTRITION	Our Ref.	MSS
Address:	CHURCH MANORWAY	Received	07-02-05
	ERITH	Started.	07-02-05
	DA8 1DL KENT	Page No:	1 of 3

Re-issue of Certificate of Analysis P5-01277B, originally issued 24th February 2005.
Reason for re-issue: Amendment of sample matrix name

ANALYSIS OF FREE WOOD STEROL PRODUCTS FOR DIOXINS

Three samples of Free Wood Sterol Products, RSSL codes, P5-01277-1 to P5-01277-3, were received for dioxin analysis The data* obtained are shown below.

P5-01277-1 (WSP: 1004004 LAB: 45121, ID: 04101301)

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Dioxin	LoD (ng g^{-1})	Conc. in sample (ng g^{-1})	TEF*	TEQ^{1}**	TEQ^{2}**
2,3,7,8-TCDF	0 0002	ND	0 100	0 0000	0 0000
1,2,3,7,8-PeCDF	0 0002	ND	0.050	0.0000	0.0000
2,3,4,7,8-PeCDF	0.0002	ND	0 500	0.0001	0.0000
1,2,3,4,7,8-HxCDF	0 0002	ND	0 100	0.0000	0.0000
1,2,3,6,7,8-HxCDF	0.0002	ND	0.100	0.0000	0.0000
2,3,4,6,7,8-HxCDF	0.0002	ND	0.100	0.0000	0.0000
1,2,3,7,8,9-HxCDF	0.0002	ND	0.100	0.0000	0.0000
1,2,3,4,6,7,8-HpCDF	0.0002	ND	0.010	0.0000	0.0000
1,2,3,4,7,8,9-HpCDF	0.0002	ND	0.010	0 0000	0.0000
OCDF	0.0002	ND	0.000	0.0000	0.0000
2,3,7,8-TCDD	0 0002	ND	1.000	0 0002	0.0000
1,2,3,7,8-PeCDD	0 0002	ND	1.000	0.0002	0.0000
1,2,3,4,7,8-HxCDD	0.0002	ND	0.100	0.0000	0.0000
1,2,3,6,7,8-HxCDD	0.0002	ND	0.100	0.0000	0 0000
1,2,3,7,8,9-HxCDD	0.0002	ND	0.100	0.0000	0.0000
1,2,3,4,6,7,8-HpCDD	0.0002	ND	0.010	0.0000	0.0000
OCDD	0 0002	0.0108	0.000	0.0000	0.0000
TEQ(WHO)			Total	0.0007	0 0000

* TEF (Toxicity Equivalent Factor) The toxicity of each dioxin is expressed relative to the toxicity of 2,3,7,8-TCDD which has a value of 1

** TEQ (Toxicity Equivalent) The concentration of each dioxin multiplied by its TEF.
TEQ^{1} = Non-detected at detection limit. TEQ^{2} = Non-detected at zero
The TEQ values are only quoted to four decimal places. The unrounded values are added together to give the totals

* These analyses were subcontracted to a laboratory that has been accredited by UKAS for this method.

ND = Not Detected, LoD = Limit of Detection

Signatories: (b) [redacted] Date: 28th February 2005

AMY SIMMONDS
Deputy Technical Manager, Flavour & Trace Laboratory

These results relate only to the sample(s) tested and do not guarantee the bulk of the material to be of equal quality
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Certificate of Analysis

Contact:	MICHELLE JONES	Report No	P5-01277B
Company	ADM NATURAL HEALTH & NUTRITION	Our Ref.	MSS
Address	CHURCH MANORWAY	Received	07-02-05
	ERITH	Started:	07-02-05
	DA8 1DL KENT	Page No:	2 of 3

ANALYSIS OF FREE WOOD STEROL PRODUCTS FOR DIOXINS

P5-01277-2 (WSP: 1004005 LAB: 49531, ID: 04111004)

Dioxin	LoD ($ng\ g^{-1}$)	Conc in sample ($ng\ g^{-1}$)	TEF*	TEQ^{1}**	TEQ^{2}**
2,3,7,8-TCDF	0.0002	ND	0.100	0.0000	0.0000
1,2,3,7,8-PeCDF	0.0002	ND	0.050	0.0000	0.0000
2,3,4,7,8-PeCDF	0.0002	ND	0.500	0.0001	0.0000
1,2,3,4,7,8-HxCDF	0.0002	ND	0.100	0.0000	0.0000
1,2,3,6,7,8-HxCDF	0.0002	ND	0.100	0.0000	0.0000
2,3,4,6,7,8-HxCDF	0.0002	ND	0.100	0.0000	0.0000
1,2,3,7,8,9-HxCDF	0.0002	ND	0.100	0.0000	0.0000
1,2,3,4,6,7,8-HpCDF	0.0002	ND	0.010	0.0000	0.0000
1,2,3,4,7,8,9-HpCDF	0.0002	ND	0.010	0.0000	0.0000
OCDF	0.0002	ND	0.001	0.0000	0.0000
2,3,7,8-TCDD	0.0002	ND	1.000	0.0002	0.0000
1,2,3,7,8-PeCDD	0.0002	ND	0.500	0.0001	0.0000
1,2,3,4,7,8-HxCDD	0.0002	ND	0.100	0.0000	0.0000
1,2,3,6,7,8-HxCDD	0.0002	ND	0.100	0.0000	0.0000
1,2,3,7,8,9-HxCDD	0.0002	ND	0.100	0.0000	0.0000
1,2,3,4,6,7,8-HpCDD	0.0002	ND	0.010	0.0000	0.0000
OCDD	0.0002	0.0182	0.001	0.0000	0.0000
TEQ(WHO)			Total	0.0006	0.0000

* TEF (Toxicity Equivalent Factor) The toxicity of each dioxin is expressed relative to the toxicity of 2,3,7,8-TCDD which has a value of 1.

** TEQ (Toxicity Equivalent) The concentration of each dioxin multiplied by its TEF
TEQ^{1} = Non-detected at detection limit. TEQ^{2} = Non-detected at zero

The TEQ values are only quoted to four decimal places. The unrounded values are added together to give the totals

† These analyses were subcontracted to a laboratory that has been accredited by UKAS for this method

ND = Not Detected, LoD = Limit of Detection

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Signatories (b) [redacted] Date: 28th February 2005

AMY SIMMONDS
Deputy Technical Manager, Flavour & Trace Laboratory

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Certificate of Analysis

Contact:	MICHELLE JONES	Report No	P5-01277B
Company:	ADM NATURAL HEALTH & NUTRITION	Our Ref.	MSS
Address:	CHURCH MANORWAY	Received	07-02-05
	ERITH	Started	07-02-05
	DA8 1DL KENT	Page No	3 of 3

ANALYSIS OF FREE WOOD STEROL PRODUCTS FOR DIOXINS

P5-01277-3 (WSP 1004006 LAB: 49532, ID: 04111005)

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Dioxin	LoD (ng g^{-1})	Conc. in sample (ng g^{-1})	TEF*	TEQ^{1}**	TEQ^{2}**
2,3,7,8-TCDF	0.0002	ND	0.100	0.0000	0.0000
1,2,3,7,8-PeCDF	0.0002	ND	0.050	0.0000	0.0000
2,3,4,7,8-PeCDF	0.0002	ND	0.500	0.0001	0.0000
1,2,3,4,7,8-HxCDF	0.0002	ND	0.100	0.0000	0.0000
1,2,3,6,7,8-HxCDF	0.0002	ND	0.100	0.0000	0.0000
2,3,4,6,7,8-HxCDF	0.0002	ND	0.100	0.0000	0.0000
1,2,3,7,8,9-HxCDF	0.0002	ND	0.100	0.0000	0.0000
1,2,3,4,6,7,8-HpCDF	0.0002	ND	0.010	0.0000	0.0000
1,2,3,4,7,8,9-HpCDF	0.0002	ND	0.010	0.0000	0.0000
OCDF	0.0002	ND	0.001	0.0000	0.0000
2,3,7,8-TCDD	0.0002	ND	1.000	0.0002	0.0000
1,2,3,7,8-PeCDD	0.0002	ND	0.500	0.0001	0.0000
1,2,3,4,7,8-HxCDD	0.0002	ND	0.100	0.0000	0.0000
1,2,3,6,7,8-HxCDD	0.0002	ND	0.100	0.0000	0.0000
1,2,3,7,8,9-HxCDD	0.0002	ND	0.100	0.0000	0.0000
1,2,3,4,6,7,8-HpCDD	0.0002	ND	0.010	0.0000	0.0000
OCDD	0.0002	0.0274	0.001	0.0000	0.0000
TEQ(WHO)			Total	0.0006	0.0000

* TEF (Toxicity Equivalent Factor) The toxicity of each dioxin is expressed relative to the toxicity of 2,3,7,8-TCDD which has a value of 1

** TEQ (Toxicity Equivalent) The concentration of each dioxin multiplied by its TEF
TEQ^{1} = Non-detected at detection limit. TEQ^{2} = Non-detected at zero.

The TEQ values are only quoted to four decimal places. The unrounded values are added together to give the totals.

† These analyses were subcontracted to a laboratory that has been accredited by UKAS for this method

ND = Not Detected, LoD = Limit of Detection

000092

Signatories (b) [redacted]

Date. 28th February 2005

AMY SIMMONDS
Deputy Technical Manager, Flavour & Trace Laboratory

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Appendix F

000092.001

Appendix F

EFSA Evaluation of Plant Sterols (Plant Sterols Containing Milk-Based Beverages, Request No. EFSA-Q-2003-075)

Pages 000094-000105 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Appendix G

Appendix G

Estimation of Phytosterol Intake by the U.S. Population from the Dietary Consumption of ADM's Proposed Food Categories

Estimation of Dietary Phytosterol Intakes from ADM's Proposed Expansion of use in Selected Food Categories in the U.S. Population

By Sam Sun, Ph.D.

Research Center of Archer Daniels Midland Company

February 22, 2005

Estimation of Dietary Phytosterol Intakes from ADM's Proposed Expansion of use in Selected Food Categories in the U.S. Population

By Sam Sun, Ph.D.

Research Center of Archer Daniels Midland Company

This estimation was conducted by using the USDA Continuing Survey of Food Intakes by Individuals (CSFII) 1994-96, 98 database (released 2000), the Code of Federal Regulations (Parts 101.12, released 2001), and the SAS software (SAS System, V9.1, SAS Institute, Cary, NC).

The major working steps in this estimation included: definition of food categories in which phytosterols are proposed to be added (totally 19 categories or groups of foods, see below); intake amounts of each selected food item were converted to servings based on "Reference amounts customarily consumed per eating occasion" found in the Code of Federal Regulations; calculation of intake levels by serving from all defined food categories using the intake data of the CSFII database; and determination of means and 90 percentiles of phytosterol intakes with phytosterol added at a level of 0.4g/serving in the defined food categories. One exemption for the calculation was edible oils in which the level of addition of sterols was considered at the 4% level. The food items in the category "Edible oils" are identical as the ones determined by CANTOX, Canada, for Enova oil (diacylglycerol oil) GRAS application in 1998. Baby food, tea, coffee, and soda are not included in the relevant food categories. Population in the database was divided into three age groups (children, 3-11 years; teenagers, 12-19 years; and adults, ≥20 years). The intake levels of selected food(s) are reported as servings per person per day (servings/person per day) and per kilogram-body-weight per day (servings/kg bw/day). The intake levels of phytosterols are reported as grams per person per day (g/person per day) and grams per kilogram-body-weight per day (g/kg bw/day). Individuals who did

not have body weight records, about 2.4% of all participants in CSFII 1994-96 and 98 databases, were not included.

The table below shows the means and 90 percentiles of individual intake levels by different age groups from the defined food categories. Only users of the proposed food categories, who were defined as an individual he/she consumed one or more than one kinds of food listed in the food categories during the survey days of the CSFII database, were included in the calculation. The 'N' represents the number of subjects. The '90pctl' in the table is the 90th percentile of intake levels as is commonly used in food consumption evaluations. Each selected food item and its corresponding code in the database are listed as part of this report.

Daily Intake levels of Food and Phytosterols from Proposed Food Categories (weighted sample, users only)
(Based on USDA CSFII DATABASE 1994-98)

Age groups (years)	Variables	N	Mean	90th Pctl
Children 3-11	Food servings/person/day	6268	4.0614	7.1144
	Food servings/kg BW/day	5868	0.1666	0.3082
	Phytosterol g/person/day	6268	1.6245	2.8457
	Phytosterol g/kg BW/day	5868	0.0667	0.1233
Teenagers 12-19	Food servings/person/day	1372	5.2115	9.8315
	Food servings/kg BW/day	1348	0.0879	0.1675
	Phytosterol g/person/day	1372	2.0846	3.9326
	Phytosterol g/kg BW/day	1348	0.0352	0.0670
Adults 20 & over	Food servings/person/day	9174	5.2286	9.7189
	Food servings/kg BW/day	9013	0.0718	0.1368
	Phytosterol g/person/day	9174	2.0915	3.8875
	Phytosterol g/kg BW/day	9013	0.0287	0.0547

Appendix: Food Categories for Sterol GRAS

1. Margarine and spread
2. Salad dressings
3. Healthy beverages
4. Healthy bars
5. Milk type products (including soy milk, ice cream, and cream substitute)
6. Cheese and cream
7. Baked foods (partial)
8. Adult type RTE breakfast cereals
9. Fruit/vegetable juices
10. Mayonnaise
11. Pasta and noodles
12. Sauces
13. Salty snacks, chips and pretzels
14. Soups, and
15. Puddings
16. Yogurt
17. Adult confections
18. Vegetarian meat analogs
19. Edible vegetable oils (includes diacylglycerol oil when used as a replacement)

The Selected Food Categories and Names for Phytosterol GRAS Expansion

(From the database of USDA Continuous Survey of Food Intake by Individuals 1994-96, 98)

1. USDA Food Codes and Names for Margarine and Spread

Food code	Food name
81102000	Margarine, NFS
81102010	Margarine, stick, salted
81102020	Margarine, tub, salted
81102030	Margarine, liquid, salted
81103020	Margarine, whipped, tub, salted
81103030	Margarine, stick, unsalted
81103040	Margarine-like spread, stick, salted
81103050	Margarine, whipped, stick, salted
81103060	Margarine, tub, unsalted
81103070	Margarine, whipped, tub, unsalted
81103080	Margarine-like spread, tub, salted
81103090	Margarine-like spread, liquid, salted
81103100	Margarine-like spread, stick, unsalted
81103120	Margarine-like spread, tub, unsalted
81103130	Margarine-like spread, whipped, tub, salted
81103140	Margarine-like spread, tub, sweetened
81104010	Margarine-like spread, reduced calorie, about 40% fat, tub, salted
81104020	Margarine-like spread, reduced calorie, about 40% fat, stick, salted

81104050	Margarine-like spread, reduced calorie, about 20% fat, tub, salted
81104070	Margarine-like spread, reduced calorie, about 20% fat, tub, unsalted
81104100	Margarine-like spread, fat free, tub, salted
81104110	Margarine-like spread, fat free, liquid, salted
81104500	Vegetable oil-butter spread, stick, salted
81104510	Vegetable oil-butter spread, tub, salted
81104550	Vegetable oil-butter spread, reduced calorie, stick, salted
81104560	Vegetable oil-butter spread, reduced calorie, tub, salted
81105010	Butter-margarine blend, stick, salted
81105020	Butter-margarine blend, tub, salted
81105030	Butter-margarine blend, stick, unsalted
81105500	Butter-vegetable oil blend
81302040	Sandwich spread
81322000	Honey butter

2. USDA Food Codes and Names for Salad Dressing

Food code	Food name
83100100	Salad dressing, NFS
83101000	Blue or roquefort cheese dressing
83101600	Bacon and tomato dressing
83102000	Caesar dressing
83104000	French dressing
83105000	Fruit dressing, made with fruit juice and cream
83105100	Fruit dressing, made with honey, oil, and water
83105500	Honey mustard dressing
83106000	Italian dressing, made with vinegar and oil
83109000	Russian dressing
83110000	Mayonnaise-type salad dressing
83110010	Mayonnaise-type salad dressing, cholesterol-free
83111000	Boiled, cooked-type dressing
83112000	Green Goddess dressing
83112500	Creamy dressing, made with sour cream and/or buttermilk and oil
83112600	Cream cheese dressing
83112900	Milk, vinegar, and sugar dressing
83112950	Poppy seed dressing
83112960	Peppercorn Dressing
83112990	Sesame dressing
83113000	Sweet and sour dressing
83114000	Thousand Island dressing
83115000	Yogurt dressing
83200100	Salad dressing, low-calorie, NFS
83200500	Bacon and tomato dressing, low calorie
83201000	Blue or roquefort cheese dressing, low-calorie
83201050	Blue or roquefort cheese dressing, reduced calorie
83201200	Blue or roquefort cheese dressing, reduced calorie, fat-free, cholesterol-free
83202000	French dressing, low-calorie
83202010	French dressing, reduced calorie, fat-free, cholesterol-free

83202020	French dressing, reduced calorie
83203000	Caesar dressing, low-calorie
83203250	Mayonnaise-type salad dressing, fat-free
83204050	Mayonnaise-type salad dressing, low-calorie or diet
83204060	Mayonnaise-type salad dressing, low-calorie or diet, cholesterol-free
83205000	Italian dressing, low calorie
83205450	Italian dressing, reduced calorie
83205500	Italian dressing, reduced calorie, fat-free
83206000	Russian dressing, low-calorie
83207000	Thousand Island dressing, low-calorie
83207100	Thousand Island dressing, reduced calorie, fat-free, cholesterol-free
83208000	Vinegar, sugar, and water dressing
83208500	Korean dressing or marinade
83209000	Milk, vinegar, and artificial sweetener dressing
83210000	Creamy dressing, made with sour cream and/or buttermilk and oil, diet, NS as to low or reduced calorie
83210050	Creamy dressing made with sour cream and/or buttermilk and oil, low calorie
83210100	Creamy dressing, made with sour cream and/or buttermilk and oil, reduced calorie
83210200	Creamy dressing, made with sour cream and/or buttermilk and oil, reduced calorie, fat-free, cholesterol-free
83210250	Creamy dressing, made with sour cream and/or buttermilk and oil, reduced calorie, cholesterol-free
83220000	Salad dressing, low calorie, oil-free

3. USDA Food codes and names for healthy beverages

Food code	Food name
92520410	Fruit drink, low calorie
92520810	Grape drink, low calorie
92530110	Apple drink with vitamin C added
92530210	Black cherry drink with vitamin C added
92530310	Cherry drink with vitamin C added
92530410	Citrus drink with vitamin C added
92530510	Cranberry juice drink with vitamin C added
92530520	Cranberry-apple juice drink with vitamin C added
92530610	Fruit punch, fruit drink, or fruitade, with vitamin C added
92530710	Grape drink with vitamin C added
92530810	Grapefruit juice drink with vitamin C added
92530950	Vegetable and fruit juice drink, with vitamin C added
92531010	Orange drink and orangeade with vitamin C added
92531020	Orange breakfast drink, made from frozen concentrate
92531030	Orange breakfast drink
92531110	Pineapple-grapefruit juice drink with vitamin C added
92531120	Pineapple-orange juice drink with vitamin C added
92531150	Pineapple-orange-grapefruit juice drink with vitamin C added
92541010	Fruit-flavored drink, made from sweetened powdered mix (fortified with vitamin C)
92541020	Lemonade-flavored drink, made from powdered mix, with sugar and vitamin C added
92541040	Lemonade-flavored drink, made from powdered mix, low calorie, with vitamin C added
92542000	Fruit-flavored drink, made from powdered mix, mainly sugar, with high vitamin C added
92544000	Fruit-flavored drink, made from unsweetened powdered mix (fortified with vitamin C), with sugar added in preparation
92550050	Apple-white grape juice drink, low calorie, with vitamin C added
92550110	Cranberry juice drink, low calorie, with vitamin C added

92550210	Cranberry-apple juice drink, low calorie, with vitamin C added
92550300	Grapefruit juice drink, low calorie, with vitamin C added
92550610	Fruit-flavored drinks, punches, ades, low calorie, with vitamin C added
92551600	Citrus juice drink, low calorie
92551700	Juice drink, low calorie
92552000	Fruit-flavored drink, made from powdered mix with high vitamin C added, low calorie
92552050	Orange breakfast drink, low calorie
92552100	Orange-cranberry juice drink, low calorie, with vitamin C added
92553000	Fruit-flavored thirst quencher beverage, low calorie
92582000	Fruit-flavored drink, low calorie, calcium fortified
92582050	Fruit-flavored drink, vitamin and mineral fortified
92582100	Citrus juice drink, calcium fortified
92582110	Orange breakfast drink, calcium fortified

4. USDA Food Codes and Names for Health Bar

Food code	Food name
41435010	High protein bar, soy base
41435110	High protein bar, candy-like, soy and milk base
41435200	High protein bar, cookie type, soy and milk base
41460010	Hi-protein wafers
53540000	Breakfast bar, NFS
53540100	Breakfast bar, cake-like
53540200	Breakfast bar, cereal crust with fruit filling, lowfat
53540500	Breakfast bar, date, with yogurt coating
53541100	Breakfast bar, diet meal type
53541200	Meal replacement bar
53542100	Granola bar, oats, sugar, raisins, coconut
53543100	Granola bar, peanuts, oats, sugar, wheat germ
53544100	Granola bar, with nougat
53544200	Granola bar, chocolate-coated
53544220	Granola bar with nuts, chocolate-coated
53544250	Granola bar, coated with non-chocolate coating
53544300	Granola bar, high fiber, coated with non-chocolate yogurt coating
53544400	Granola bar, with rice cereal

5. USDA Food Codes and Names for Milk Type Products (Includes Soy Milk, Ice Cream, and Cream Substitutes)

Food code	Food name
11211050	Milk, evaporated, whole, NS as to dilution, used in coffee or tea
11212050	Milk, evaporated, skim, NS as to dilution, used in coffee or tea
11213050	Milk, evaporated, filled with vegetable oil, NS as to dilution, used in coffee or tea
11310000	Milk, imitation, fluid, soy based

11320000	Milk, soy, ready-to-drink, not baby's
11330000	Milk, soy, dry, reconstituted, not baby's
11514300	Cocoa with nonfat dry milk and low calorie sweetener, mixture, water added
11515400	Cocoa with nonfat dry milk and low calorie sweetener, high calcium, water added
11516000	Cocoa, whey, and low-calorie sweetener mixture, lowfat milk added
11518000	Milk beverage with nonfat dry milk and low calorie sweetener, water added, chocolate
11518050	Milk beverage with nonfat dry milk and low calorie sweetener, water added, flavors other than chocolate
11518100	Milk beverage with nonfat dry milk and low calorie sweetener, high calcium, water added, chocolate
11552200	Milk-based fruit drink
11553000	Fruit smoothie drink, made with fruit or fruit juice and dairy products
11553100	Fruit smoothie drink, NFS
11560000	Chocolate-flavored drink, whey- and milk-based
11560020	Flavored milk drink, whey- and milk-based, flavors other than chocolate
11560100	Flavored milk drink, skim milk and cream-based, flavors other than chocolate
11560110	Chocolate-flavored milk drink, skim milk and cream-based
11611000	Instant breakfast, fluid, canned
11612000	Instant breakfast, powder, milk added
11613000	Instant breakfast, powder, sweetened with low calorie sweetener, milk added
11621000	Diet beverage, liquid, canned
11622000	Diet beverage, powder, milk added
11622010	Diet beverage, powder, reconstituted with skim milk
11623000	Meal supplement or replacement, commercially prepared, ready-to-drink
11631000	High calorie beverage, canned or powdered, reconstituted
11641000	Meal supplement or replacement, milk-based, high protein, liquid
11651010	Meal replacement formula, Cambridge diet, reconstituted, all flavors
11830100	Cocoa (or chocolate) with dry milk and sugar, dry mix, not reconstituted
11830110	Cocoa powder with nonfat dry milk and low calorie sweetener, dry mix, not reconstituted
11830120	Cocoa, whey, and low calorie sweetener, fortified, dry mix, not reconstituted
11830140	Chocolate, instant, dry mix, fortified with vitamins and minerals, not reconstituted, Puerto Rican style
11830150	Cocoa powder, not reconstituted (no dry milk)
11830160	Cocoa (or chocolate) flavored beverage powder with sugar, dry mix, not reconstituted
11830170	Cocoa, whey, and low-calorie sweetener mixture, not reconstituted
11830180	Cocoa (or chocolate) flavored beverage powder with low calorie sweetener, dry mix, not reconstituted
11830500	Milk beverage, powder, with nonfat dry milk and low calone sweetener, dry mix, not reconstituted, chocolate
11830550	Milk beverage, powder, with nonfat dry milk and low calone sweetener, dry mix, not reconstituted, flavors other than chocolate
11830800	Instant breakfast, powder, not reconstituted
11830810	Instant breakfast, powder, sweetened with low calorie sweetener, not reconstituted
11830850	High calorie milk beverage, powder, not reconstituted
11830900	Protein supplement, milk-based, powdered, not reconstituted
11830940	Meal replacement, high protein, milk based, fruit juice mixable formula, powdered, not reconstituted
11830950	Nutrient supplement, milk-based, powdered, not reconstituted
11830960	Protein supplement, milk-based, sodium controlled, powdered, not reconstituted
11830970	Meal replacement, protein type, milk-based, powdered, not reconstituted
11830980	Protein supplement, milk-based, powdered, not reconstituted
11830990	Nutrient supplement, milk-based, powdered, not reconstituted
11831500	Nutrient supplement, milk-based, high protein, powdered, not reconstituted
11832000	Meal replacement, protein type, milk- and soy-based, powdered, not reconstituted
11832500	Meal replacement, protein type, milk-based, with sugar and artificial sweetener, not reconstituted
11835000	Meal replacement or nutritional supplement, Cambridge diet formula, powdered, nonfat milk solids base, dry, not recon- stituted
11835100	Meal replacement, Amway's Nutrilite brand Positrim Drink Mix, powdered nonfat dry milk-based, dry, not reconstituted

12200100	Cream substitute, liquid or powder
12210200	Cream substitute, liquid
12210250	Cream substitute, light, liquid
12210400	Cream substitute, powder
12210410	Cream substitute, light, powder
13110000	Ice cream, NFS
13110100	Ice cream, regular, flavors other than chocolate
13110110	Ice cream, regular, chocolate
13110120	Ice cream, rich, flavors other than chocolate
13110130	Ice cream, rich, chocolate
13110140	Ice cream, rich, NS as to flavor
13110200	Ice cream, soft serve, flavors other than chocolate
13110210	Ice cream, soft serve, chocolate
13110220	Ice cream, soft serve, NS as to flavor
13120050	Ice cream bar or stick, not chocolate covered or cake covered
13120100	Ice cream bar or stick, chocolate covered
13120110	Ice cream bar or stick, chocolate or caramel covered, with nuts
13120120	Ice cream bar or stick, rich chocolate ice cream, thick chocolate covering
13120121	Ice cream bar or stick, rich ice cream, thick chocolate covering
13120130	Ice cream bar or stick, rich ice cream, chocolate covered, with nuts
13120140	Ice cream bar or stick, chocolate ice cream, chocolate covered
13120300	Ice cream bar, cake covered
13120400	Ice cream bar or stick with fruit
13120500	Ice cream sandwich
13120550	Ice cream cookie sandwich
13120700	Ice cream cone with nuts, flavors other than chocolate
13120710	Ice cream cone, chocolate covered, with nuts, flavors other than chocolate
13120720	Ice cream cone, chocolate covered or dipped, flavors other than chocolate
13120730	Ice cream cone, no topping, flavors other than chocolate
13120740	Ice cream cone, no topping, NS as to flavor
13120750	Ice cream cone with nuts, chocolate ice cream
13120760	Ice cream cone, chocolate covered or dipped, chocolate ice cream
13120770	Ice cream cone, no topping, chocolate ice cream
13120780	Ice cream cone, chocolate covered, with nuts, chocolate ice cream
13120790	Ice cream sundae cone
13120800	Ice cream soda, flavors other than chocolate
13120810	Ice cream soda, chocolate
13121000	Ice cream sundae, NS as to topping, with whipped cream
13121100	Ice cream sundae, fruit topping, with whipped cream
13121200	Ice cream sundae, prepackaged type, flavors other than chocolate
13121300	Ice cream sundae, chocolate or fudge topping, with whipped cream
13121400	Ice cream sundae, not fruit or chocolate topping, with whipped cream
13121500	Ice cream sundae, fudge topping, with cake, with whipped cream
13122100	Ice cream pie, no crust
13122500	Ice cream pie, with cookie crust, fudge topping, and whipped cream
13124100	Sorbet and ice cream
13125100	Ice cream with sherbet
13126000	Ice cream, fried
13130100	Light ice cream, NFS (formerly ice milk)

13130300	Light ice cream, flavors other than chocolate (formerly ice milk)
13130310	Light ice cream, chocolate (formerly ice milk)
13130350	Light ice cream, premium, flavors other than chocolate (formerly ice milk)
13130360	Light ice cream, premium, chocolate (formerly ice milk)
13130370	Light ice cream, premium, NS as to flavor (formerly ice milk)
13130590	Light ice cream, soft serve, NS as to flavor (formerly ice milk)
13130600	Light ice cream, soft serve, flavors other than chocolate (formerly ice milk)
13130610	Light ice cream, soft serve, chocolate (formerly ice milk)
13130620	Light ice cream, soft serve cone, flavors other than chocolate (formerly ice milk)
13130630	Light ice cream, soft serve cone, chocolate (formerly ice milk)
13130640	Light ice cream, soft serve cone, NS as to flavor (formerly ice milk)
13135000	Light ice cream, sandwich (formerly ice milk)
13140100	Light ice cream, bar or stick, chocolate-coated (formerly ice milk)
13140110	Light ice cream, bar or stick, chocolate covered, with nuts (formerly ice milk)
13140450	Light ice cream, cone, NFS (formerly ice milk)
13140500	Light ice cream, cone, flavors other than chocolate (formerly ice milk)
13140550	Light ice cream, cone, chocolate (formerly ice milk)
13140600	Light ice cream, sundae, soft serve, chocolate or fudge topping, with whipped cream (f
13140630	Light ice cream, sundae, soft serve, fruit topping, with whipped cream (formerly ice m
13140650	Light ice cream, sundae, soft serve, not fruit or chocolate topping, with whipped crea
13140660	Light ice cream, sundae, soft serve, chocolate or fudge topping (without whipped cream
13140670	Light ice cream, sundae, soft serve, fruit topping (without whipped cream) (formerly i
13140680	Light ice cream, sundae, soft serve, not fruit or chocolate topping (without whipped c
13140700	Light ice cream, creamsicle or dreamsicle (formerly ice milk)
13140900	Light ice cream, fudgesicle (formerly ice milk)
13141100	Light ice cream, with sherbet or ice cream (formerly ice milk)
13161630	Light ice cream, bar or stick, with low-calorie sweetener, chocolate-coated (formerly

6. USDA Food Codes and Names for Cheese and Cream

Food code	Food name
12100100	Cream, NS as to light, heavy, or half and half
12110100	Cream, light, fluid
12110300	Cream, light, whipped, unsweetened
12120100	Cream, half and half
12130100	Cream, heavy, fluid
12130200	Cream, heavy, whipped, unsweetened
12140000	Cream, heavy, whipped, sweetened
12140100	Cream, whipped, pressurized container
12200100	Cream substitute, NS as to frozen, liquid, or powdered
12210100	Cream substitute, frozen
12210200	Cream substitute, liquid
12210250	Cream substitute, light, liquid
12210400	Cream substitute, powdered
12210410	Cream substitute, light, powdered
12310100	Sour cream

12310200	Sour cream, half and half
12310300	Sour cream, reduced fat
12310350	Sour cream, light
12310370	Sour cream, fat free
12320100	Sour cream, imitation (nondairy)
12320200	Sour cream, filled, sour dressing, nonbutterfat
12350000	Dip, sour cream base
12350020	Dip, sour cream base, reduced calorie
12350100	Spinach dip, sour cream base
13411000	White sauce, milk sauce
14010000	Cheese, NFS
14010100	Cheese, Cheddar or American type, NS as to natural or processed
14100100	Cheese, natural, NFS
14101010	Cheese, Blue or Roquefort
14102010	Cheese, Brick
14102110	Cheese, Brick, with salami
14103010	Cheese, Camembert
14103020	Cheese, Brie
14104010	Cheese, natural, Cheddar or American type
14104020	Cheese, Cheddar or American type, dry, grated
14104200	Cheese, Colby
14104250	Cheese, Colby Jack
14104400	Cheese, Feta
14104600	Cheese, Fontina
14104700	Cheese, goat
14105010	Cheese, Gouda or Edam
14105200	Cheese, Gruyere
14106010	Cheese, Limburger
14106200	Cheese, Monterey
14106500	Cheese, Monterey, lowfat
14107010	Cheese, Mozzarella, NFS
14107020	Cheese, Mozzarella, whole milk
14107030	Cheese, Mozzarella, part skim
14107040	Cheese, Mozzarella, low sodium
14107060	Cheese, Mozzarella, nonfat or fat free
14107200	Cheese, Muenster
14107210	Cheese, Muenster, low sodium
14107250	Cheese, Muenster, lowfat
14108010	Cheese, Parmesan, dry grated
14108020	Cheese, Parmesan, hard
14108050	Cheese, Parmesan, low sodium
14108060	Parmesan cheese topping, fat free
14108200	Cheese, Port du Salut
14108400	Cheese, Provolone
14108410	Cheese, Provolone, reduced fat, reduced sodium
14108800	Cheese, Semi-soft, low sodium
14109010	Cheese, Swiss
14109020	Cheese, Swiss, low sodium
14109030	Cheese, Swiss, lowfat
14110010	Cheese, Cheddar or Colby, low sodium

14110020	Cheese, Cheddar or Colby, low sodium, lowfat
14110030	Cheese, Cheddar or Colby, lowfat
14131000	Queso Anejo (aged Mexican cheese)
14131500	Queso Asadero
14132000	Queso Chihuahua
14133000	Queso Fresco
14200100	Cheese, cottage, NFS
14201010	Cheese, cottage, creamed, large or small curd
14201500	Cheese, Ricotta
14202010	Cheese, cottage, with fruit
14202020	Cheese, cottage, with vegetables
14203010	Cheese, cottage, dry curd
14203020	Cheese, cottage, salted, dry curd
14203510	Puerto Rican white cheese (queso del pais, blanco)
14301010	Cheese, cream
14303010	Cheese, cream, lowfat
14410100	Cheese, processed, American and Swiss blends
14410200	Cheese, processed, American or Cheddar type
14410210	Cheese, processed, American or Cheddar type, low sodium
14410300	Cheese, processed, American or Cheddar type, lowfat
14410310	Cheese, processed, American, Cheddar, or Colby, lowfat, low sodium
14410330	Cheese, processed cheese product, American or Cheddar type, reduced fat
14410340	Cheese, processed cheese product, American or Cheddar type, reduced fat, reduced sodium
14410350	Cheese, processed, American or Cheddar type, nonfat or fat free
14410380	Cheese, processed cream cheese product, nonfat or fat free
14410400	Cheese, processed, Swiss
14410410	Cheese, processed, Swiss, low sodium
14410420	Cheese, processed, Swiss, lowfat
14410440	Cheese, processed, Swiss, lowfat, low sodium
14410450	Cheese, processed cheese product, Swiss, reduced fat
14410500	Cheese, processed cheese food
14410600	Cheese, processed, with vegetables
14410620	Cheese, processed, with wine
14410710	Cheese, processed, Mozzarella, low sodium
14410830	Cheese, processed, Muenster, lowfat, low sodium
14420000	Cheese spread, NFS
14420100	Cheese spread, American or Cheddar cheese base
14420140	Cheese spread, American or Cheddar cheese base, lowfat, low sodium
14420160	Cheese spread, Swiss cheese base
14420200	Cheese spread, cream cheese or Neufchatel base
14420300	Cheese spread, pressurized can
14501010	Imitation cream cheese
14502010	Imitation cheese, American or cheddar type
14502040	Imitation cheese, American or cheddar type, low cholesterol
14503010	Imitation cheese spread
14504010	Imitation mozzarella cheese
14610520	Cheese with nuts
14620100	Dip, cream cheese base
14620120	Shrimp dip, cream cheese base
14620150	Dip, cheese with chili pepper (chili con queso)

14620200	Dip, cheese base other than cream cheese
14630100	Cheese fondue

7. USDA Food Codes and Names for Baked Food (partial)

Food code	Food name
51000100	Bread, NS as to major flour
51000200	Roll, NS as to major flour
51101000	Bread, white
51109100	Bread, pita
51122000	Bread, reduced calorie and/or high fiber, white or NFS
51123010	Bread, high protein
51127010	Bread, potato
51129010	Bread, raisin
51150000	Roll, white, soft
51153000	Roll, white, hard
51155000	Roll, French or Vienna
51157000	Roll, hoagie, submarine
51159000	Roll, sour dough
51166000	Croissant
51180010	Bagel
51186010	Muffin, English
51201010	Bread, whole wheat, 100%
51201150	Bread, pita, whole wheat, 100%
51202000	Muffin, English, whole wheat, 100%
51208000	Bagel, whole wheat, 100%
51220000	Roll, whole wheat, 100%
51301700	Bagel, wheat
51302500	Muffin, English, wheat bran
51401010	Bread, rye
51404010	Bread, pumpernickel
51404500	Bagel, pumpernickel
51404550	Muffin, English, pumpernickel
51420000	Roll, rye
51421000	Roll, pumpernickel
51503000	Muffin, English, oat bran
51601020	Bread, multigrain
51630000	Bagel, multigrain
51630200	Muffin, English, multigrain
51804010	Bread, soy
52101100	Biscuit, baking powder or buttermilk type, made from mix
52104040	Biscuit, whole wheat
52301000	Muffin, NFS
52303500	Muffin, wheat
52304010	Muffin, wheat bran
52306010	Muffin, plain

8. USDA Food Codes and Names for Adult Type RTE Breakfast Cereals

Food code	Food name
56207190	Whole wheat cereal, cooked, NS as to fat added in cooking
56207200	Whole wheat cereal, cooked, fat not added in cooking
56207210	Whole wheat cereal, cooked, fat added in cooking
56207220	Wheat, cream of, cooked, regular, fat added in cooking
56207230	Wheat, cream of, cooked, quick, fat added in cooking
56207290	Wheat hearts, cooked, NS as to fat added in cooking
56207300	Whole wheat cereal, wheat and barley, cooked, fat not added in cooking
56207310	Wheat hearts, cooked, fat not added in cooking
56207330	Whole wheat cereal, wheat and barley, cooked, fat added in cooking
56207340	Whole wheat cereal, wheat and barley, cooked, NS as to fat added in cooking
56207350	Wheat cereal, chocolate flavored, cooked, made with milk
56207360	Wheat cereal, chocolate flavored, cooked, fat not added in cooking
56207370	Wheat cereal, chocolate flavored, cooked, NS as to fat added in cooking
56208000	Multigrain cereal, cooked, fat not added in cooking
56208010	Multigrain cereal, cooked, fat added in cooking
56208020	Multigrain cereal, cooked, NS as to fat added in cooking
56208500	Oat bran cereal, cooked, fat not added in cooking
56208510	Oat bran cereal, cooked, fat added in cooking
56208520	Oat bran cereal, cooked, NS as to fat added in cooking
56208530	Oat bran cereal, cooked, made with milk, fat not added in cooking
56208540	Oat bran cereal, cooked, made with milk, fat added in cooking
56208550	Oat bran cereal, cooked, made with milk, NS as to fat added in cooking
56209000	Rye, cream of, cooked
57000000	Cereal, NFS
57000050	Kashi cereal, NS as to ready to eat or cooked
57000100	Oat cereal, NFS
57100100	Cereal, ready-to-eat, NFS
57101000	All-Bran
57101020	All-Bran with Extra Fiber
57101500	Almond Delight
57102000	Alpen
57103050	Amaranth Flakes
57103100	Apple Cinnamon Cheerios
57103400	Apple Cinnamon Oh's Cereal
57103500	Apple Cinnamon Squares Mini-Wheats, Kellogg's (formerly Apple Cinnamon Squares)
57105000	Apple Raisin Crisp
57106050	Banana Nut Crunch Cereal (Post)
57106100	Basic 4
57106530	Blueberry Morning, Post
57110000	All-Bran Bran Buds, Kellogg's (formerly Bran Buds)
57111000	Bran Chex
57112000	Branola
57123000	Cheerios
57124000	Chex cereal, NFS

57125900	Honey Nut Clusters (formerly called Clusters)
57128880	Common Sense Oat Bran, plain
57128900	Common Sense Oat Bran, with raisins
57131000	Crunchy Corn Bran, Quaker
57132000	Corn Chex
57134000	Corn flakes, NFS
57134090	Corn flakes, low sodium
57135000	Corn flakes, Kellogg
57138000	Total Corn Flakes
57143000	Cracklin' Oat Bran
57144000	Crisp Crunch
57148000	Crispix
57148500	Crispy Brown Rice Cereal
57151000	Crispy Rice
57152000	Crispy Wheats'n Raisins
57205250	Double Chex
57206000	Familia
57206700	Fiber One
57206800	Fiber 7 Flakes, Health Valley
57207000	Bran Flakes, NFS (formerly 40% Bran Flakes, NFS)
57208000	Complete Wheat Bran Flakes, Kellogg's (formerly 40% Bran Flakes)
57209000	Natural Bran Flakes, Post (formerly called 40% Bran Flakes, Post)
57210100	40+ Bran Flakes
57213800	Frosted Bran, Kellogg's
57219000	Fruit & Fibre (fiber), NFS
57220000	Fruit & Fibre (fiber) with apples and cinnamon
57221000	Fruit & Fibre (fiber) with dates, raisins, and walnuts
57221600	Fruit & Fibre (fiber) with peaches, raisins, almonds and oat clusters
57222500	Fruit Wheats
57225000	Golden Harvest Proteinola
57227000	Granola, NFS
57228000	Granola, homemade
57229000	Granola, lowfat, Kellogg's
57229500	Granola with Raisins, lowfat, Kellogg's
57230000	Grape-Nuts
57231000	Grape-Nut Flakes
57231200	Great Grains, Raisin, Date, and Pecan Whole Grain Cereal, Post
57231250	Great Grains Double Pecan Whole Grain Cereal, Post
57232100	Healthy Choice Almond Crunch with raisins, Kellogg's
57232110	Healthy Choice Multi-Grain Squares, Kellogg's
57232120	Healthy Choice Multi-Grain Flakes, Kellogg's
57233000	Heartland Natural Cereal, plain
57234000	Heartland Natural Cereal, with raisins
57235000	Heartland Natural Cereal, with coconut
57237100	Honey Bunches of Oats
57237300	Honey Bunches of Oats with Almonds, Post
57238000	Honeycomb, plain
57240000	Honey Graham Chex
57240100	Honey Nut Chex
57241000	Honey Nut Cheerios

57241200	Honey Nut Shredded Wheat, Post
57243870	Jenny O's
57244000	Just Right
57245000	Just Right Fruit and Nut (formerly Just Right with raisins, dates, and nuts)
57302100	King Vitaman
57304100	Life (plain and cinnamon)
57307500	Millet, puffed
57307550	Mini Buns Cereal (cinnamon)
57308150	Mueslix cereal, NFS
57308160	Mueslix with raisins, walnuts, and cranberries
57308170	Muesli with raisins, peaches, and pecans
57308180	Mueslix Crispy Blend (formerly Mueslix Five Grain Muesli Cereal)
57308190	Muesli with raisins, dates, and almonds
57308200	Mueslix golden crunch cereal
57308210	Muesli with apples and almonds, Ralston Purina
57308220	Strawberry muesli with pecans and raisins, Ralston
57308300	Multi Bran Chex
57308400	Multi Grain Cheerios
57308410	Multi-Grain Cheerios Plus
57308900	Natural Muesli, Jenny's Cuisine
57309100	Nature Valley Granola, with fruit and nuts
57310000	Nature Valley Granola, with cinnamon and raisins
57311000	Nature Valley Granola, toasted oat mixture
57311700	Nu System Cuisine Toasted Grain Circles
57311800	Nut and Honey Crunch (flakes)
57312100	Nutri-Grain Biscuits, Whole Grain Shredded Wheat Cereal
57315000	Nutri-Grain Golden Wheat (formerly Nutri-Grain Wheat)
57316100	Nutri-Grain Almond Raisin
57316200	Nutty Nuggets, Ralston Purina
57316300	Oat Bran Flakes, Health Valley
57316700	Oh's, Crunchy Nut
57316710	Oh's, Honey Graham
57316750	Oh's, Fruitangy, Quaker
57317000	Oat flakes, fortified
57317200	Oat Flakes, Post
57318000	100% Bran
57319000	100% Natural Cereal, plain, Quaker
57319500	Sun Country 100% Natural Granola, with Almonds
57320500	100 % Natural Cereal, with oats, honey and raisins, Quaker
57321000	100% Natural Cereal, with raisins and dates, Quaker
57321500	100 % Natural Wholegrain Cereal with raisins, lowfat, Quaker
57322500	Oreo O's cereal, Post
57325000	Product 19
57327450	Quaker Oat Bran Cereal
57327500	Quaker Oatmeal Squares (formerly Quaker Oat Squares)
57328000	Quisp
57329000	Raisin bran, NFS
57330000	Raisin Bran, Kellogg
57330500	Raisin Bran, Nutri System
57331000	Raisin Bran, Post

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57332000	Raisin Bran, Ralston Purina
57332050	Raisin Bran, Total
57332100	Raisin Nut Bran
57332300	Super Raisin Bran, New Morning
57333000	Raisin Grape-Nuts
57334000	Raisin Life
57335500	Raisin Squares Mini-Wheats, Kellogg's (formerly Raisin Squares)
57336000	Rice Chex
57337000	Rice Flakes, NFS
57340200	Ripple Crisp Golden Corn
57340210	Ripple Crisp Honey Bran, General Mills
57341000	Shredded Wheat'N Bran
57344000	Special K
57346500	Toasted Oatmeal, Honey Nut (Quaker)
57347500	Strawberry Squares Mini-Wheats, Kellogg's (formerly Strawberry Squares)
57354000	Sun Flakes
57401100	Toasted oat cereal
57402000	Team
57402600	Temptations, French Vanilla Almond, Kellogg's
57402610	Temptations, Honey Roasted Pecan, Kellogg's
57403100	Toasties, Post
57404100	Malt-O-Meal Toasty O's
57406100	Total
57406200	Triples
57408100	Uncle Sam's Hi Fiber Cereal
57410000	Weetabix Whole Wheat Cereal
57411000	Wheat Chex
57412000	Wheat germ, plain
57413000	Wheat germ, with sugar and honey
57417000	Shredded Wheat, 100%
57417500	Shredded Wheat with Oat Bran
57418000	Wheaties
57418200	Wheaties, Honey Frosted (formerly Wheaties Honey Gold)

9. USDA Food Codes and Names for Fruit and vegetable Juice

Food code	Food name
61201000	Grapefruit juice, NFS
61201020	Grapefruit juice, unsweetened, NS as to form
61201220	Grapefruit juice, canned, bottled or in a carton, unsweetened
61201230	Grapefruit juice, canned, bottled or in a carton, with sugar
61201240	Grapefruit juice, canned, bottled, or in a carton, sweetened with low calorie sweetener
61201620	Grapefruit juice, frozen, unsweetened (reconstituted with water)
61201630	Grapefruit juice, frozen, with sugar (reconstituted with water)
61210000	Orange juice, NFS
61210220	Orange juice, canned, bottled or in a carton, unsweetened
61210230	Orange juice, canned, bottled or in a carton, with sugar
61210250	Orange juice, with calcium added, canned, bottled or in a carton, unsweetened
61210620	Orange juice, frozen, unsweetened (reconstituted with water)

61210630	Orange juice, frozen, with sugar (reconstituted with water)
61210720	Orange juice, frozen, unsweetened, not reconstituted
61210730	Orange juice, frozen, with sugar, not reconstituted
61210820	Orange juice, frozen, with calcium added (reconstituted with water)
61213000	Tangerine juice, NFS
61213220	Tangerine juice, canned, unsweetened
61213230	Tangerine juice, canned, with sugar
61213620	Tangerine juice, frozen, unsweetened (reconstituted with water)
61214000	Grape-tangerine-lemon juice
61216000	Grapefruit and orange juice, NFS
61216220	Grapefruit and orange juice, canned, unsweetened
61216230	Grapefruit and orange juice, canned, with sugar
61216620	Grapefruit and orange juice, frozen (reconstituted with water)
61219000	Orange and banana juice
61219100	Pineapple-orange-banana juice
61219150	Orange-white grape-peach juice
61219650	Apricot-orange juice
61222000	Pineapple-grapefruit juice, NFS
61222200	Pineapple-grapefruit juice, canned, bottled or in a carton, NS as to sweetened or unsweetened
61222220	Pineapple-grapefruit juice, canned, bottled or in a carton, unsweetened
61222230	Pineapple-grapefruit juice, canned, bottled or in a carton, with sugar
61222600	Pineapple-grapefruit juice, frozen (reconstituted with water)
61225000	Pineapple-orange juice, NFS
61225200	Pineapple-orange juice, canned, NS as to sweetened or unsweetened; sweetened, NS as to type of sweetener
61225220	Pineapple-orange juice, canned, unsweetened
61225230	Pineapple-orange juice, canned, with sugar
61225600	Pineapple-orange juice, frozen (reconstituted with water)
64100100	Fruit juice, NFS
64100110	Fruit juice blend, 100% juice, with added Vitamin C
64104600	Blackberry juice
64105400	Cranberry juice, unsweetened
64105500	Cranberry-white grape juice mixture, unsweetened
64116010	Grape juice, NS as to added sweetener
64116020	Grape juice, unsweetened
64116030	Grape juice, with sugar
64116040	Grape juice, low-calorie sweetener
64116050	Grape juice, NS as to sweetened or unsweetened, with added vitamin C
64116100	Grape juice, unsweetened, with added vitamin C
64116150	Grape juice, with sugar, with added vitamin C
64120010	Papaya juice
64121000	Passion fruit juice
64122030	Peach juice, with sugar
64124010	Pineapple juice, NS as to sweetened or unsweetened
64124020	Pineapple juice, unsweetened
64124030	Pineapple juice, with sugar
64124060	Pineapple juice, unsweetened, with added Vitamin C
64124200	Pineapple-apple-guava juice, with added vitamin C
64125000	Pineapple juice-non-citrus juice blend, unsweetened, with added vitamin C
64132010	Prune juice, NS as to added sweetener
64132020	Prune juice, unsweetened

64132030	Prune juice, with sugar
74301150	Tomato juice, low sodium
74302000	Tomato juice cocktail
74303000	Tomato and vegetable juice, mostly tomato
74303100	Tomato and vegetable juice, mostly tomato, low sodium
74304000	Tomato juice with clam or beef juice

10. USDA Food Codes and Names for Mayonnaise

Food code	Food name
83107000	Mayonnaise, regular
83107100	Mayonnaise, made with yogurt
83107200	Mayonnaise, made with tofu
83108000	Mayonnaise, imitation
83108100	Mayonnaise, imitation, cholesterol free
83204000	Mayonnaise, low-calorie or diet
83204010	Mayonnaise, low-calorie or diet, low sodium
83204020	Mayonnaise, reduced calorie or diet, cholesterol-free

11. USDA Food Codes and Names for Pasta and Noodles

Food code	Food name
56101000	Macaroni, cooked, NS as to fat added in cooking
56101010	Macaroni, cooked, fat not added in cooking
56101030	Macaroni, cooked, fat added in cooking
56104000	Macaroni, cooked, vegetable, NS as to fat added in cooking
56104010	Macaroni, cooked, vegetable, fat not added in cooking
56104020	Macaroni, cooked, vegetable, fat added in cooking
56112000	Noodles, cooked, NS as to fat added in cooking
56112010	Noodles, cooked, fat not added in cooking
56112030	Noodles, cooked, fat added in cooking
56130000	Spaghetti, cooked, NS as to fat added in cooking
56130010	Spaghetti, cooked, fat not added in cooking
56131000	Spaghetti, cooked, fat added in cooking
56132000	Spaghetti, cooked, high protein type (assume no fat added)
56139990	Pasta, cooked, corn-based, NS as to fat added in cooking
56140000	Pasta, cooked, corn-based, fat not added in cooking
58130010	Lasagna with meat and/or poultry
58130013	Lasagna with meat, canned
58130020	Lasagna with meat and spinach
58130150	Lasagna, with chicken or turkey, and spinach
58130310	Lasagna, meatless
58130320	Lasagna, meatless, with spinach
58130910	Lasagna with meat, spinach noodles
58130950	Lasagna, meatless, spinach noodles

58132110	Spaghetti with tomato sauce, meatless
58132310	Spaghetti with tomato sauce and meatballs or spaghetti with meat sauce
58132450	Spaghetti with tomato sauce, meatless, made with spinach noodles
58132460	Spaghetti with tomato sauce and meatballs made with spinach noodles
58133110	Manicotti, cheese-filled, no sauce
58133140	Manicotti, vegetable- and cheese-filled, with tomato sauce, meatless
58134110	Stuffed shells, cheese-filled, no sauce
58134160	Stuffed shell, cheese- and spinach- filled, no sauce
58134650	Tortellini, meat-filled, no sauce
58134680	Tortellini, cheese-filled, no sauce
58134720	Tortellini, spinach-filled, no sauce
58134810	Cannelloni, cheese- and spinach-filled, no sauce
58145110	Macaroni or noodles with cheese
58147510	Flavored pasta
58148550	Pasta salad with meat (macaroni or noodles, vegetables, meat, dressing)
58148600	Pasta tetrazzini, dry mix, prepared with water
58301010	Lasagna with cheese, tomato sauce, vegetable, dessert (frozen meal)
58301020	Lasagna with cheese and sauce (diet frozen meal)
58301030	Veal lasagna (diet frozen meal)
58301050	Lasagna with cheese and meat sauce (diet frozen meal)
58301080	Lasagna with cheese and meat sauce, reduced fat and sodium (diet frozen meal)
58301110	Vegetable lasagna (frozen meal)
58301130	Tuna lasagna (diet frozen meal)
58301150	Zucchini lasagna (diet frozen meal)
58302000	Macaroni and cheese (diet frozen meal)
58302010	Macaroni and cheese with apples, vegetable (frozen meal)
58302030	Macaroni with veal, cheese, and sauce (diet frozen meal)
58302040	Macaroni with beef in tomato-based sauce, vegetable, and dessert (frozen meal)
58302060	Spaghetti or noodles with beef in tomato-based sauce, lowfat, reduced sodium (diet frozen meal)
58302080	Noodles with vegetables in tomato-based sauce (diet frozen meal)
58304010	Spaghetti and meatballs dinner, NFS (frozen meal)
58304020	Spaghetti and meatballs with tomato sauce, sliced apples, bread (frozen meal)
58304030	Spaghetti and meatballs with vegetable, dessert (frozen meal)
58304050	Spaghetti with meat and mushroom sauce (diet frozen meal)
58304060	Spaghetti with meat sauce (diet frozen meal)
58304220	Rigatoni with meat sauce and cheese (diet frozen meal)
58304250	Manicotti, cheese-filled, with tomato sauce (diet frozen meal)
58304300	Cannelloni, cheese-filled, with tomato sauce (diet frozen meal)
58304350	Linguini with clam sauce (diet frozen meal)
58304400	Linguini with vegetables and seafood in white wine sauce (diet frozen meal)
58305010	Mosticolli with meatballs, sauce, bread (frozen meal)
58305100	Macaroni or noodles, spinach, with chicken and cheese sauce (diet frozen meal)
58305200	Pasta, spinach, with vegetables and cheese sauce (diet frozen meal)
58305250	Pasta with vegetable and cheese sauce (diet frozen meal)
58306800	Noodles and chicken with gravy, vegetable, and dessert (frozen meal)
58307010	Beef and pork cannelloni (diet frozen meal)

12. USDA Food Codes and Names for Sauces

Food code	Food name
13411000	White sauce, milk sauce
14650100	Cheese sauce
14650150	Cheese sauce made with lowfat cheese
14650160	Alfredo sauce
27111000	Beef with tomato-based sauce (mixture)
27150140	Clam sauce, white
27150190	Lobster sauce (broth-based)
27150200	Oyster sauce (white sauce-based)
27150210	Fish sauce (bagoong)
27162050	Spaghetti sauce with combination of meats, homemade-style
28520100	Oyster-flavored sauce
41420100	Miso sauce
41420250	Hoisin sauce
41420300	Soy sauce
41420350	Soy sauce, reduced sodium
41420400	Teriyaki sauce
41420410	Teriyaki sauce, reduced sodium
41420450	Worcestershire sauce
42204050	Peanut sauce
43103100	Sesame sauce
74401010	Tomato catsup
74401110	Tomato catsup, low sodium
74402010	Tomato chili sauce (catsup-type)
74402100	Salsa, NFS
74402150	Salsa, red, cooked, not homemade
74402250	Enchilada sauce, red
74402260	Enchilada sauce, green
74402350	Green tomato-chile sauce, cooked (Salsa verde, NFS)
74403010	Tomato sauce
74403050	Tomato sauce, low sodium
74403110	Tomato paste
74403120	Tomato puree
74404010	Spaghetti sauce
74404030	Spaghetti sauce with meat, canned, no extra meat added
74404050	Spaghetti sauce, low sodium
74404060	Spaghetti sauce, fat free
74405010	Tomato relish
74406010	Barbecue sauce
74406050	Barbecue sauce, low sodium
74406100	Steak sauce, tomato-base
74406500	Cocktail sauce
75506010	Mustard
75506100	Mustard sauce
75511010	Peppers, hot, sauce

81301020	Lemon-butter sauce
81302010	Hollandaise sauce
81302020	Bernaise sauce
81302030	Orange sauce (for duck)
81302040	Sandwich spread
81302050	Tartar sauce
81312000	Tartar sauce, low calorie
81302060	Horseradish sauce
81302070	Pesto sauce
91304050	Hard sauce
91361010	Sweet and sour sauce
91361030	Raisin sauce
91361050	Duck sauce

13. USDA Food Codes and Names for Salty Snacks, Chips and Pretzels

Food code	Food name
54401020	Salty snacks, corn or cornmeal base, corn chips, corn-cheese chips
54401050	Salty snacks, corn or cornmeal base, corn puffs and twists; corn-cheese puffs and twists
54401080	Salty snacks, corn or cornmeal base, tortilla chips
54401090	Salty snacks, corn or cornmeal base, corn chips, corn-cheese chips, unsalted
54401100	Salty snacks, corn or cornmeal base, tortilla chips, light (baked with less oil)
54401120	Salty snacks, corn or cornmeal base, tortilla chips, fat free, made with Olean
54401150	Salty snacks, corn or cornmeal base, tortilla chips, lowfat, baked without fat
54401170	Salty snacks, corn or cornmeal base, tortilla chips, lowfat, baked without fat, unsalted
54401200	Salty snacks, corn or cornmeal base, with oat bran, tortilla chips
54401210	Salty snacks, corn based puffs and twists, cheese puffs and twists, lowfat
54402080	Salty snacks, corn or cornmeal base, tortilla chips, unsalted
54402200	Salty snack mixture, mostly corn or cornmeal based, with pretzels, without nuts
54402300	Salty snacks, wheat-based, high fiber
54402500	Salty snacks, wheat- and corn-based chips
54402600	Salty snacks, multigrain, chips
54408000	Pretzels, NFS
54408010	Pretzels, hard
54408020	Pretzels, soft
54408030	Pretzel, hard, unsalted
54408050	Pretzel, oatbran, hard
54408070	Pretzel, hard, multigrain
54408200	Pretzel, hard, chocolate-coated
54408250	Pretzel, yogurt-covered
54408300	Pretzels, cheese-filled
54412110	Wheat sticks, 100% whole wheat
54420010	Multigrain mixture, pretzels, cereal and/or crackers, nuts
54420200	Multigrain mixture, bread sticks, sesame nuggets, pretzels, rye chips

54430010	Yogurt chips
54440010	Bagel chip
71201050	White potato, chips, reduced fat
71201080	White potato, chips, fat free
71201090	White potato chips, fat free, made with Olean
71201200	White potato, chips, restructured, reduced fat and reduced sodium
71201210	White potato, chips, restructured, fat free, made with Olean
71201250	White potato, chips, restructured, baked
71201300	Potato based snacks, reduced fat, low sodium, all flavors
71202000	White potato, chips, unsalted
71202100	White potato, chips, unsalted, reduced fat
71204000	Potato puffs, cheese-filled

14. USDA Food Codes and Names for Soups

Food code	Food name
28310150	Oxtail soup
28310160	Beef broth, with tomato, home recipe
28310170	Beef broth, without tomato, home recipe
28310210	Chili beef soup
28310220	Chili beef soup, chunky style
28310230	Meatball soup, Mexican style (Sopa de Albondigas)
28310320	Beef noodle soup, Puerto Rican style (Sopa de carne
28310330	Beef and rice noodle soup, Oriental style (Vietname
28310420	Beef and rice soup, Puerto Rican style
28315100	Beef vegetable soup with potato, stew type
28315110	Beef noodle soup, chunky style
28315120	Beef vegetable soup with noodles, stew type, chunky
28315130	Beef vegetable soup with rice, stew type, chunky st
28315140	Beef vegetable soup, Mexican style (Sopa / caldo de
28316020	Beef and mushroom soup, canned, low sodium
28317010	Beef stroganoff soup, chunky style
28320110	Pork and rice soup, stew type, chunky style
28320120	Pork vegetable soup with noodles, stew type, chunky
28320130	Ham, rice, and potato soup, Puerto Rican style
28320140	Ham, noodle, and vegetable soup, Puerto Rican style
28320150	Pork, vegetable soup with potatoes, stew type
28320300	Pork with vegetable (excluding carrots, broccoli an
28321130	Bacon soup, cream of, prepared with water
28330110	Scotch broth (lamb, vegetables, and barley)
28331110	Lamb, pasta, and vegetable soup, Puerto Rican style
28340210	Chicken rice soup, Puerto Rican style (Sopa de poll
28340220	Chicken soup with noodles and potatoes, Puerto Rica
28340310	Chicken gumbo soup
28340510	Chicken noodle soup, chunky style
28340520	Chicken soup, canned, undiluted

28340530	Chicken soup
28340550	Sweet and sour soup
28340580	Chicken soup with vegetables (broccoli, carrots, ce
28340590	Chicken corn soup, home recipe
28340610	Chicken or turkey vegetable soup, stew type
28340620	Turkey noodle soup, chunky style
28340630	Chicken vegetable soup with rice, stew type, chunky
28340640	Chicken vegetable soup with noodles, stew type, chu
28340650	Chicken vegetable soup with rice, stew type, chunky
28340660	Chicken or turkey vegetable soup, home recipe
28340670	Chicken vegetable soup with rice, Mexican style (So
28340690	Chicken vegetable soup with potato and cheese, chun
28340700	Bird's nest soup (chicken, ham, and noodles)
28340750	Hot and sour soup
28340800	Chicken soup with vegetables and fruit, Oriental St
28345010	Chicken or turkey soup, cream of, canned, NS as to
28345020	Chicken or turkey soup, cream of, canned, made with
28345030	Chicken or turkey soup, cream of, canned, made with
28345040	Chicken or turkey soup, cream of, canned, undiluted
28345110	Chicken or turkey soup, cream of, NS as to prepared
28345120	Chicken or turkey soup, cream of, prepared with mil
28345130	Chicken or turkey soup, cream of, prepared with wat
28345140	Chicken or turkey soup, cream of, canned, undiluted
28345160	Chicken and mushroom soup, cream of, prepared with
28345170	Duck soup
28350040	Fish stock, home recipe
28350050	Fish chowder
28350110	Crab soup, NS as to tomato-base or cream style
28350120	Crab soup, tomato-base
28350210	Clam chowder, NS as to Manhattan or New England sty
28350220	Clam chowder, Manhattan
28351110	Fish and vegetable soup, no potatoes (Sopa de pesca
28351120	Fish soup, with potatoes (Sopa de Pescado)
28351160	Codfish, rice, and vegetable soup, Puerto Rican sty
28351170	Codfish soup with noodles, Puerto Rican style
28355110	Clam chowder, New England, NS as to prepared with w
28355120	Clam chowder, New England, prepared with milk
28355130	Clam chowder, New England, prepared with water
28355140	Clam chowder, New England, canned, reduced sodium, ready-to-serve
28355210	Crab soup, cream of, prepared with milk
28355250	Lobster bisque
28355260	Lobster gumbo
28355310	Oyster stew
28355350	Salmon soup, cream style
28355410	Shrimp soup, cream of, NS as to prepared with milk
28355420	Shrimp soup, cream of, prepared with milk
28355430	Shrimp soup, cream of, prepared with water
28355440	Shrimp gumbo
28355450	Seafood soup with potatoes and vegetables (includin
28355460	Seafood soup with potatoes and vegetables (excludin

28355470	Seafood soup with vegetables (including carrots, br
28355480	Seafood soup with vegetables (excluding carrots, br
28360100	Meat broth, Puerto Rican style (Caldo)
28360210	Spanish vegetable soup, Puerto Rican style (Caldo g
32301100	Garlic egg soup, Puerto Rican style (Sopa de ajo)
41601010	Bean soup, NFS
41601020	Bean with bacon or pork soup
41601030	Black bean soup
41601040	Lima bean soup
41601050	Soybean soup, made with milk
41601060	Bean soup, with macaroni and meat
41601070	Soybean soup, miso broth
41601080	Pinto bean soup
41601090	Bean soup, with macaroni
41601100	Portuguese bean soup
41601110	Bean and ham soup, chunky style
41601120	Bean soup with vegetables, rice, and pork
41601130	Bean soup, mixed beans
41601140	Bean soup, home recipe
41601150	Bean soup with vegetables and rice, canned, reduced
41601160	Bean and ham soup, canned, reduced sodium, prepared
41601170	Bean and rice soup
41601180	Bean and ham soup, home recipe
41601200	Liquid from stewed kidney beans, Puerto Rican style
41602010	Chunky pea and ham soup
41602020	Garbanzo or chickpea soup
41602030	Split pea and ham soup
41602040	Pea soup, instant type
41602050	Split pea soup
41602060	Pigeon pea asopao
41602070	Split pea soup, canned, reduced sodium, prepared wi
41602090	Split pea and ham soup, canned, reduced sodium, pre
41603010	Lentil soup
41610100	White bean soup, Puerto Rican style (Sopon de habic
58407030	Soup, mostly noodles
58408010	Won ton (wonton) soup
58408500	Noodle soup with vegetables, Oriental style
58409000	Noodle soup, with fish ball, shrimp, and dark green
58410100	Rice soup, made with tea
58450300	Noodle soup, made with milk

15. USDA Food Codes and Names for Pudding

Food code	Food name
13200110	Pudding, NFS
13210110	Pudding, bread
13210150	Puerto Rican bread pudding made with evaporated milk and rum (Budin de pan)
13210160	Diplomat pudding, Puerto Rican style (Budin Diplomatico)

13210180	Pudding, Mexican bread (Capirotada)
13210190	Pudding, Mexican bread (Capirotada), lower fat
13210220	Pudding, chocolate, ready-to-eat, NS as to from dry mix or canned
13210250	Pudding, chocolate, ready-to-eat, low calorie, containing artificial sweetener, NS as to from dry mix or canned
13210260	Rice flour cream, Puerto Rican style (Majarete, manjar blanco)
13210270	Spanish custard, Puerto Rican style (Natilla Espanol)
13210280	Pudding, flavors other than chocolate, ready-to-eat, NS as to from dry mix or canned
13210290	Pudding, flavors other than chocolate, ready-to-eat, low calorie, containing artificial sweetener, NS as to from dry mix or canned
13210300	Custard
13210350	Custard, Puerto Rican style (Flan)
13210410	Pudding, rice
13210450	Pudding, rice flour, with nuts (Indian dessert)
13210500	Pudding, tapioca, made from home recipe, made with milk
13210520	Pudding, tapioca, made from dry mix, made with milk
13210530	Pudding, tapioca, chocolate, made with milk
13210610	Pudding, coconut
13210710	Pudding, Indian (milk, molasses and cornmeal-based pudding)
13210750	Pudding, pumpkin
13210810	Puerto Rican pumpkin pudding (Flan de calabaza)
13210820	Fresh corn custard, Puerto Rican style (Mazamorra, Mundo Nuevo)
13220110	Pudding, flavors other than chocolate, prepared from dry mix, milk added
13220120	Pudding, chocolate, prepared from dry mix, milk added
13220210	Pudding, flavors other than chocolate, prepared from dry mix, low calorie, containing artificial sweetener, milk added
13220220	Pudding, chocolate, prepared from dry mix, low calorie, containing artificial sweetener, milk added
13220230	Pudding, canned, chocolate, reduced fat
13220235	Pudding, canned, chocolate, fat free
13220240	Pudding, canned, flavors other than chocolate, reduced fat
13220245	Pudding, canned, flavors other than chocolate, fat free
13230110	Pudding, canned, flavors other than chocolate
13230120	Pudding, canned, low calorie, containing artificial sweetener, flavors other than chocolate
13230130	Pudding, canned, chocolate
13230140	Pudding, canned, low calorie, containing artificial sweetener, chocolate
13230200	Pudding, canned, chocolate and non-chocolate flavors combined
13230500	Pudding, canned, tapioca
13230510	Pudding, canned, tapioca, fat free
13235000	Pudding pops, chocolate
13235100	Pudding pops, flavors other than chocolate
13236000	Pudding roll-up, chocolate
13236100	Pudding roll-up, flavors other than chocolate
13240110	Pudding, sodium-controlled, with milk base
13241000	Pudding, with fruit and vanilla wafers
13250000	Mousse, chocolate
13250100	Mousse, not chocolate
13250200	Mousse, chocolate, lowfat, reduced calorie, prepared from dry mix, water added
13251000	Chantilly Cream
13252100	Coconut custard, Puerto Rican style (Flan de coco)
13252200	Milk dessert or milk candy, Puerto Rican style (Dulce de leche)
13252500	Barfi or Burfi, Indian dessert, made from milk and/or cream and/or Ricotta cheese
91520100	Yookan (Yokan), a Japanese dessert made with bean paste and sugar
91550100	"Tastes good to me", Puerto Rican style (Bien me sabe)

91550300	Pineapple custard, Puerto Rican style (Flan de pina)
91560100	Haupia (coconut pudding)

16. USDA Food Codes and Names for Yogurt

Food code	Food name
11410000	Yogurt, NS as to type of milk or flavor
11411010	Yogurt, plain, NS as to type of milk
11411100	Yogurt, plain, whole milk
11411200	Yogurt, plain, lowfat milk
11411300	Yogurt, plain, nonfat milk
11420000	Yogurt, vanilla, lemon, or coffee flavor, NS as to type of milk
11421000	Yogurt, vanilla, lemon, or coffee flavor, whole milk
11422000	Yogurt, vanilla, lemon, maple, or coffee flavor, lowfat milk
11423000	Yogurt, vanilla, lemon, maple, or coffee flavor, nonfat milk
11424000	Yogurt, vanilla, lemon, maple, or coffee flavor, nonfat milk, sweetened with low calorie sweetener
11425000	Yogurt, chocolate, NS as to type of milk
11426000	Yogurt, chocolate, whole milk
11427000	Yogurt, chocolate, nonfat milk
11430000	Yogurt, fruit variety, NS as to type of milk
11431000	Yogurt, fruit variety, whole milk
11432000	Yogurt, fruit variety, lowfat milk
11433000	Yogurt, fruit variety, nonfat milk
11433500	Yogurt, fruit variety, nonfat milk, sweetened with low-calorie sweetener
11444000	Yogurt, fruit and nuts, NS as to type of milk
11445000	Yogurt, fruit and nuts, lowfat milk

17. USDA Food Codes and Names for Confections

Food code	Food name
91701010	Almonds, chocolate covered
91701030	Almonds, yogurt-covered
91703500	Nuts, carob-coated
91705020	Chocolate, milk, with cereal
91705040	Chocolate, milk, with nuts, not almond or peanuts
91705050	Chocolate, milk, with fruit and nuts
91705060	Chocolate, milk, with almonds
91705070	Chocolate, milk, with peanuts
91705090	Chocolate with fondant and caramel
91705200	Chocolate, semi-sweet morsel
91705410	Chocolate, white, with almonds
91705420	Chocolate, white, with cereal
91708100	Fruit snack candy, with added vitamin C
91713010	Fudge, chocolate, chocolate-coated
91713020	Fudge, chocolate, chocolate-coated, with nuts
91713030	Fudge, chocolate

91713040	Fudge, chocolate, with nuts
91713050	Fudge, peanut butter
91713060	Fudge, peanut butter, with nuts
91713070	Fudge, vanilla
91713080	Fudge, vanilla, with nuts
91713090	Fudge, divinity
91713100	Fudge, brown sugar (penuche)
91715000	Fudge, caramel and nut, chocolate-coated
91727010	Nuts, chocolate covered, not almonds or peanuts
91728000	Nut roll, fudge or nougat, caramel and nuts
91728500	Sugared pecans (sugar and egg white coating)
91731000	Peanuts, chocolate covered
91731100	Peanuts, sugar-coated
91731150	Peanuts, yogurt covered
91732000	Peanut bar
91732100	Planters Peanut Bar
91733200	Peanut Bar, chocolate covered
91733500	Peanut Butter Boppers
91734000	Peanut butter, chocolate covered
91734500	Peanut butter morsels
91735000	Pralines
91739010	Raisins, chocolate covered
91739510	Raisins, carob covered
91739600	Raisins, yogurt covered
91742010	Sesame Crunch (Sahadi)
91746010	Sugar-coated chocolate discs

18. USDA Food Codes and Names for Vegetarian Meat Analogs

Food code	Food name
41440000	Textured vegetable protein, dry
41812600	Vegetarian, fillet
41812850	Vegetarian stroganoff (made with meat substitute)
41812900	Vegetarian meat loaf or patties (meat loaf made with meat substitute)
41813000	Vegetarian bouillon, dry
41811910	Vegetable burger or patty, meatless, no bun

19. Food Codes and Names for "edible oil" category generated by CANTOX

Food code	Food name
21003000	Beef, NS as to cut, fried, NS to fat eaten
21103110	Beef steak, breaded or floured, baked or fried, NS as to fat eaten
21103120	Beef steak, breaded or floured, baked or fried, lean and fat eaten
21103130	Beef steak, breaded or floured, baked or fried, lean only eaten
22000300	Pork, NS as to cut, breaded or floured, fried, NS as to fat eaten

22000310	Pork, NS as to cut, breaded or floured, fried, lean and fat eaten
22000320	Pork, NS as to cut, breaded or floured, fried, lean only eaten
22002100	Pork, ground or patty, breaded, cooked
22101300	Pork chop, breaded or floured, fried, NS as to fat eaten
22101310	Pork chop, breaded or floured, fried, lean and fat eaten
22101320	Pork chop, breaded or floured, fried, lean only eaten
22201400	Pork steak or cutlet, breaded or floured, fried, NS as to fat eaten
22201410	Pork steak or cutlet, breaded or floured, fried, lean and fat eaten
22201420	Pork steak or cutlet, breaded or floured, fried, lean only eaten
22210310	Pork, tenderloin, breaded, fried
22300120	Ham, fried, NS as to fat eaten
22300130	Ham, fried, lean and fat eaten
22300140	Ham, fried, lean only eaten
22300150	Ham, breaded or floured, fried, NS as to fat eaten
22300160	Ham, breaded or floured, fried, lean and fat eaten
22300170	Ham, breaded or floured, fried, lean only eaten
22709010	Pork skin, rinds, deep-fried
23321250	Venison/deer steak, breaded or floured, cooked, NS as to cooking method
24156250	Chicken, thigh, with or without bone, breaded, baked or fried, prepared skinless, coating eaten
24198710	Chicken patty with cheese, breaded, cooked
24198840	Chicken crackling, Puerto Rican style (Chicharron de pollo)
24302010	Duck, pressed, Chinese
25120150	Heart, fried
25150210	Brains and eggs, cooked
25160130	Tongue pot roast, Puerto Rican style (Lengua al caldero)
26129150	Pike, battered, fried
26131150	Pompano, battered, fried
26133150	Porgy, battered, fried
27111000	Beef with tomato-based sauce (mixture)
27111050	Spaghetti sauce with beef or meat other than lamb or mutton, homemade-style
27111200	Beef burgundy
27111300	Mexican style beef stew, no potatoes, tomato-based sauce (mixture) (Carne guisada sin papas)
27111310	Mexican style beef stew, no potatoes, with chili peppers, tomato-based sauce (mixture) (Carne guisada con chile)
27115000	Beef with soy-based sauce (mixture)
27115100	Steak teriyaki with sauce (mixture)
27116300	Beef with sweet and sour sauce (mixture)
27118110	Meatballs, Puerto Rican style (Albondigas)
27118120	Stewed seasoned ground beef, Puerto Rican style (Picadillo guisado, picadillo de carne)
27118130	Stewed dried beef, Puerto Rican style (Tasajo guisado, carne cecina guisada)
27118140	Stuffed pot roast, Puerto Rican style, NFS (assume with gravy and stuffing)
27118180	Puerto Rican style beef stew, meat with gravy (potatoes reported separately)
27120080	Ham stroganoff
27120100	Ham or pork with tomato-based sauce (mixture)
27121010	Stewed pork, Puerto Rican style
27130040	Spaghetti sauce with lamb or mutton, homemade-style
27130100	Lamb curry
27141000	Chicken or turkey cacciatore
27141050	Stewed chicken with tomato-based sauce, Mexican style (mixture) (Pollo guisado con tomate)
27146050	Chicken wing with hot pepper sauce
27146300	Chicken or turkey parmigiana

27150140	Clam sauce, white
27150250	Fish moochim (Korean style), dried fish with soy sauce
27151040	Crabs in tomato-based sauce, Puerto Rican style (mixture) (Salmorejo de jueyes)
27151050	Shrimp in garlic sauce, Puerto Rican style (mixture) (Camarones al ajillo)
27151070	Stewed codfish, Puerto Rican style
27161010	Puerto Rican style meat loaf (Albondigon)
27162050	Spaghetti sauce with combination of meats, homemade-style
27211110	Mexican style beef stew with potatoes, tomato-based sauce (mixture) (Carne guisada con papas)
27211300	Beef (roast) hash
27212350	Beef stroganoff with noodles
27214300	Beef wellington
27218110	Puerto Rican style stuffed pot roast (larded meat) (Carne mechada con papas boliche)
27218210	Puerto-Rican style beef stew (Carne guisada con papas)
27218310	Stewed corned beef, Puerto Rican style ("Corned beef" guisado)
27221100	Stewed pig's feet, Puerto Rican style (Patitas de cerdo guisadas)
27221110	Pork roast, stuffed, Puerto Rican style
27221150	Mexican style pork stew, with potatoes, tomato-based sauce (mixture) (cerdo guisado con papas)
27250820	Fish and rice with cream sauce
27250950	Shellfish mixture and noodles, tomato-based sauce (mixture)
27251010	Stewed salmon, Puerto Rican style (Salmon guisado)
27260050	Meatballs, with breading, NS as to type of meat, with gravy
27261000	Breaded brains, Puerto Rican style (Sesos rebosados)
27313150	Beef, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), soy-based sauce (mixture)
27313160	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), soy-based sauce (mixture)
27315270	Stuffed grape leaves with beef and rice
27315510	Beef, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), soy-based sauce (mixture)
27315520	Beef, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), soy-based sauce (mixture)
27320080	Sausage, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce
27320090	Sausage, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce
27320310	Pork chow mein or chop suey with noodles
27330170	Stuffed grape leaves with lamb and rice
27330210	Lamb or mutton stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce
27331150	Veal fricassee, Puerto Rican style (ternera en fricase)
27335500	Stewed rabbit, Puerto Rican style (Fricase de conejo)
27343910	Chicken or turkey chow mein or chop suey with noodles
27348100	Chicken fricassee, Puerto Rican style (Fricase de pollo)
27350020	Paella with seafood
27350110	Bouillabaisse
27351010	Codfish with starchy vegetables, Puerto Rican style (Serenata de bacalao) (mixture)
27351020	Codfish salad, Puerto Rican style (Gazpacho de bacalao)
27351030	Stewed codfish, Puerto Rican style (Bacalao guisado)
27351040	Biscayne codfish, Puerto Rican style (Bacalao a la Vizcaina)
27351050	Codfish salad, Puerto Rican style (Ensalada de bacalao)
27360090	Paella, NFS
27360100	Brunswick stew
27362000	Stewed tripe, Puerto Rican style, with potatoes (Mondongo)
27411120	Swiss steak
27415100	Beef and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)
27415120	Beef, tofu, and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)
27416100	Beef and vegetables, Hawaiian style (mixture)

27416150	Pepper steak
27418110	Seasoned shredded soup meat (Ropa vieja, sopa de carne ripiada)
27418210	Puerto-Rican style beef stew (Carne a la Judia)
27418310	Corned beef with tomato sauce and onion, Puerto Rican style (mixture)
27418410	Beef steak with onions, Puerto Rican style (mixture) (Biftec encebollado)
27420110	Pork and vegetables, Hawaiian style (mixture)
27420120	Pork and watercress with soy-based sauce (mixture)
27420170	Pork and onions with soy-based sauce (mixture)
27420500	Pork and vegetables (including carrots, broccoli, and/or dark-green leafy), soy-based sauce (mixture)
27420510	Pork and vegetables (excluding carrots, broccoli, and dark- green leafy), soy-based sauce (mixture)
27421010	Stuffed christophine, Puerto Rican style (Chayote relleno)
27422010	Pork chop stewed with vegetables, Puerto Rican style (mixture) (Chuletas a la jardinera)
27445110	Chicken or turkey and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)
27445120	Chicken or turkey and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce (mixture)
27445150	General Tso (General Gau) chicken
27448010	Chicken or turkey fricassee, no potatoes, Puerto Rican style, NFS (assume with sauce)
27448020	Chicken or turkey fricassee, with sauce, no potatoes, Puerto Rican style (potatoes reported separately)
27448030	Chicken or turkey fricassee, no sauce, no potatoes, Puerto Rican style (sauce and potatoes reported separately)
27450080	Seafood salad
27450410	Shrimp and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)
27450420	Shrimp and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce (mixture)
27450600	Shellfish mixture and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce
27450610	Shellfish mixture and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce
27450740	Fish and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)
27450750	Fish and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce (mixture)
27451010	Fish a la creole, Puerto Rican style (Pescado frito con mojo)
27451030	Lobster creole, Puerto Rican style (Langosta a la criolla)
27451070	Codfish salad, Puerto Rican style (Serenata)
27461010	Stewed seasoned ground beef, Puerto Rican style (Picadillo para relleno)
27462000	Stewed chitterlings, Puerto Rican style (cuajo guisado)
28350310	Turtle and vegetable soup
28351110	Fish and vegetable soup, no potatoes (Sopa de pescado)
28351120	Fish soup, with potatoes (Sopa de Pescado)
28351160	Codfish, rice, and vegetable soup, Puerto Rican style
28351170	Codfish soup with noodles, Puerto Rican style
28510010	Gravy or sauce, poultry-based from Puerto Rican-style chicken fricasse
28510020	Gravy, meat-based, from Puerto-Rican style stuffed pot roast
32105180	Huevos rancheros
32105310	Ripe plantain omelet, Puerto Rican style (Tortilla de amarillo)
32105330	Scrambled eggs with jerked beef, Puerto Rican style (Revoltillo de tasajo)
32301100	Garlic egg soup, Puerto Rican style (Sopa de ajo)
35001000	Scrambled eggs, sausage, hash brown potatoes (frozen meal)
41205050	Bean dip, made with refried beans
41205100	Black bean sauce
41209000	Falafil
41210100	Stewed dry red beans, Puerto Rican style (Habichuelas coloradas guisadas)
41210110	Stewed dry lima beans, Puerto Rican style
41210120	Stewed white beans, Puerto Rican style
41210150	Stewed pink beans with viandas, ham, Puerto Rican style
41210160	Stewed pink beans with pig's feet, Puerto Rican style

41210170	Stewed red beans with pig's feet, Puerto Rican style
41210180	Stewed white beans with pig's feet, Puerto Rican style
41210190	Stewed red beans with pig's feet and potatoes, Puerto Rican style
41210200	Black beans, Cuban style (Habichuelas negras guisadas a la Cubana)
41303500	Stewed green peas, Puerto Rican style (Habichuelas del pais)
41303550	Stewed green peas with pig's feet and potatoes, Puerto Rican style
41306000	Loaf, lentil
41310100	Stewed pigeon peas, Puerto Rican style (Gandules guisados, Gandur, Gandules)
41310150	Stewed chickpeas, Puerto Rican style
41310160	Stewed chickpeas, with potatoes, Puerto Rican style
41310200	Chickpeas stewed with pig's feet, Puerto Rican style (Garbanzos guisados con patitos de cerdo)
41310210	Stewed chickpeas with Spanish sausages, Puerto Rican style (Garbanzos guisados con chorizos)
41601050	Soybean soup, made with milk
41601070	Soybean soup, miso broth
41601090	Bean soup, with macaroni
41601110	Bean and ham soup, chunky style
41602060	Pigeon pea asopao
41610100	White bean soup, Puerto Rican style (Sopon de habichuelas blancas)
41811950	Swiss steak, with gravy, meatless
41812850	Vegetarian stroganoff (made with meat substitute)
55310100	Bread fritters, Puerto Rican style (Torrejas, Galician fritters)
55601000	Flour and milk patty
56205200	Rice, frozen dessert, nondairy, flavors other than chocolate
56205410	Rice, white, cooked with (fat) oil, Puerto Rican style (Arroz blanco)
58100150	Burrito with beef and potato, no beans
58100360	Chilaquiles, tortilla casserole with salsa, cheese, and egg
58100370	Chilaquiles, tortilla casserole with salsa and cheese, no egg
58101930	Taco or tostada salad with beef and cheese, fried flour tortilla
58109000	Italian pie, meatless
58109010	Italian pie with meat
58112510	Dumpling, steamed, filled with meat, poultry, or seafood
58115110	Tamale casserole, Puerto Rican style (Tamales en cazuela)
58115150	Tamal in a leaf, Puerto Rican style (Tamales en hoja)
58115210	Taco with crab meat, Puerto Rican style (Taco de jueye)
58116110	Meat turnover, Puerto Rican style (Pastelillo de carne; Empanadilla)
58116310	Cheese turnover, Puerto Rican style (Pastelillo de queso; Empanadilla)
58117210	Cornmeal stick, Puerto Rican style (Surullo)
58117510	Hallaca, Puerto Rican style (hominy, pork or ham, vegetables)
58123110	Manapua, filled with meat
58123120	Manapua, filled with bean paste, meatless
58124250	Spanakopitta
58132800	Spaghetti with clam sauce, NS as to red or white
58132810	Spaghetti with red clam sauce
58132820	Spaghetti with white clam sauce
58134630	Tortellini, cheese-filled, meatless, with vegetables and vinaigrette dressing
58134640	Tortellini, cheese-filled, meatless, with vinaigrette dressing
58134810	Cannelloni, cheese- and spinach-filled, no sauce
58135110	Chow fun noodles with meat and vegetables
58135120	Chow fun noodles with vegetables, meatless
58140110	Spaghetti with corned beef, Puerto Rican style

58145110	Macaroni or noodles with cheese
58147100	Pasta with pesto sauce
58150110	Rice, fried, meatless
58150310	Rice, fried, NFS
58150510	Rice, fried, with shrimp
58155210	Stuffed rice with chicken, Dominican style (Arroz relleno Dominicano)
58155310	Paella, Valenciana style, with meat (Paella Valenciana)
58155320	Seafood paella, Puerto Rican style (Paella a la marinera)
58155410	Soupy rice with chicken, Puerto Rican style (Asopao de pollo)
58155910	Rice with squid, Puerto Rican style (arroz con calamares)
58156110	Fried rice, Puerto Rican style (arroz frito)
58156710	Rice with stewed beans, Puerto Rican style
58161510	Grape leaves stuffed with rice
58175110	Tabbouleh (bulgar with tomatoes and parsley)
58404500	Matzo ball soup
58407030	Soup, mostly noodles
58408010	Won ton (wonton) soup
58408500	Noodle soup with vegetables, Oriental style
58409000	Noodle soup, with fish ball, shrimp, and dark green leafy vegetable
58410100	Rice soup, made with tea
58421000	Sopa seca (dry soup), Mexican style, NFS
58421010	Sopa Seca de Fideo, Mexican style, made with dry noodles
58421060	Sopa seca de arroz (dry rice soup), Mexican style
58450300	Noodle soup, made with milk
59003000	Meat substitute, cereal- and vegetable protein-based, fried
71403000	White potato, home fries
71703000	Stewed potatoes, Mexican style (Papas guisadas)
71703040	Stewed potatoes with tomatoes, Mexican style (Papas guisadas con tomate)
71704000	Stewed potatoes with tomatoes
71900200	Plantain, fried, NS as to green or ripe
71901110	Fried green plantain, Puerto Rican style (Tostones)
71905110	Fried ripe plantain, Puerto Rican style (Platano maduro frito)
71905120	Plantain, ripe, rolled in flour, fried
71931010	Cassava with creole sauce, Puerto Rican style (Yuca al mojo)
72202030	Broccoli, batter-dipped and fried
72308500	Dark-green leafy vegetable soup, meatless, Oriental style
73111400	Carrots in tomato sauce
74410110	Sofrito, Puerto Rican seasoning
74415110	Tomato and sofrito stewing sauce, Puerto Rican style
74420110	Puerto Rican ground seasoning
75142550	Cucumber salad made with cucumber, oil, and vinegar
75201030	Artichoke salad in oil
75208520	Breadfruit, fried
75226040	Peppers, red, cooked, NS as to fat added in cooking
75226110	Peppers, hot, cooked, NS as to form, fat added in cooking
75316050	Ratatouille
75340300	Pinacbet (eggplant with tomatoes, bitter melon, etc.)
75400500	Artichokes, stuffed
75409020	Cauliflower, batter-dipped, fried
75412030	Eggplant dip

75418010	Squash, summer, yellow or green, breaded or battered, fried
75439500	Chop suey, meatless
75440400	Vegetables, dipped in chick-pea flour batter, (pakora), fried
75506100	Mustard sauce
77121010	Fried stuffed potatoes, Puerto Rican style (Rellenos de papas)
77121110	Potato and ham fritters, Puerto Rican style (Frituras de papa y jamon)
77141010	Potato chicken pie, Puerto Rican style (Pastelon de pollo)
77201210	Green plantain with cracklings, Puerto Rican style (Mofongo)
77205110	Ripe plantain fritters, Puerto Rican style (Pionono)
77205610	Ripe plantain meat pie, Puerto Rican style (Pinon)
77230210	Cassava Pasteles, Puerto Rican style (Pasteles de yuca)
77230510	Cassava pie stuffed with crab meat, Puerto Rican style (Empanada de jueyes)
77250110	Stuffed tannier fritters, Puerto Rican style (Alcapurrias)
77250710	Tannier fritters, Puerto Rican style (Frituras de yautia)
77272010	Puerto Rican pasteles (Pasteles de masa)
77316010	Stuffed cabbage, with meat, Puerto Rican style (Repollo relleno con carne)
77316510	Stuffed cabbage, with meat and rice, Syrian dish, Puerto Rican style (Repollo relleno con carne y con arroz; Arabe Mihsy Melful)
77316600	Eggplant and meat casserole
77563010	Puerto Rican stew (Sancocho)
81302040	Sandwich spread
81302070	Pesto sauce
82101000	Vegetable oil, NFS
82101300	Almond oil
82101500	Coconut oil
82102000	Corn oil
82102500	Corn and canola oil
82103000	Cottonseed oil
82103500	Flaxseed oil
82104000	Olive oil
82105000	Peanut oil
82105500	Rapeseed oil
82105750	Canola and soybean oil
82105800	Canola, soybean and sunflower oil
82106000	Safflower oil
82107000	Sesame oil
82108000	Soybean oil
82108250	Soybean and sunflower oil
82108500	Sunflower oil
82108700	Walnut oil
82109000	Wheat germ oil

Appendix H

000140.001

Appendix H

A Review of the Safety of Sucrose Fatty Acid Esters used in the Emulsification of Plant Sterols in Selected Food Applications

Regulatory and Safety Review of

Sucrose Fatty Acid Esters as Emulsifiers in Foods

In support of the GRAS determination

of expanded use of phytosterols

Regulatory and Safety Review on Sucrose Fatty Acid Esters As Emulsifiers in Foods

Introduction

This review is for the purpose of determining the safe use of sucrose fatty acid esters (SFAE) as an emulsifier of phytosterols intended for use in selected food applications.

Product description of sucrose fatty acid esters

Sucrose fatty acid esters, also known as sucrose esters of fatty acids, consists of a mixture of mono, di- and triesters of sucrose with fatty acids derived from edible fats or oils. It has an INS number of 473. They are prepared from sucrose; the methyl and ethyl esters of edible fatty acids; or edible naturally occurring vegetable oils in the presence of food-grade solvents such as ethyl acetate, methyl ethyl ketone, dimethyl-sulfoxide, or isobutanol. They occur as stiff gels, soft solids, or white to slightly grayish white powders and are odorless. They are soluble in ethanol and depending on the monoester percentages, sparingly soluble in water. Their functional use in foods are as emulsifier, stabilizer and texturizer. The substance specifications include not less than 80.0% of the combined mono-, di-, and triesters of sucrose, and not more than 5% of free sucrose (FCC, 1997).

Sucrose fatty acid esters are food additives permitted for use as emulsifiers and stabilizers for oil/water emulsions in a variety of processed foods (21CFR 172.859, *Appen*dix 1). Sucrose fatty acid esters have been commercially manufactured at reasonably high volumes since the early 1960s (Drummond et. al., 2003).

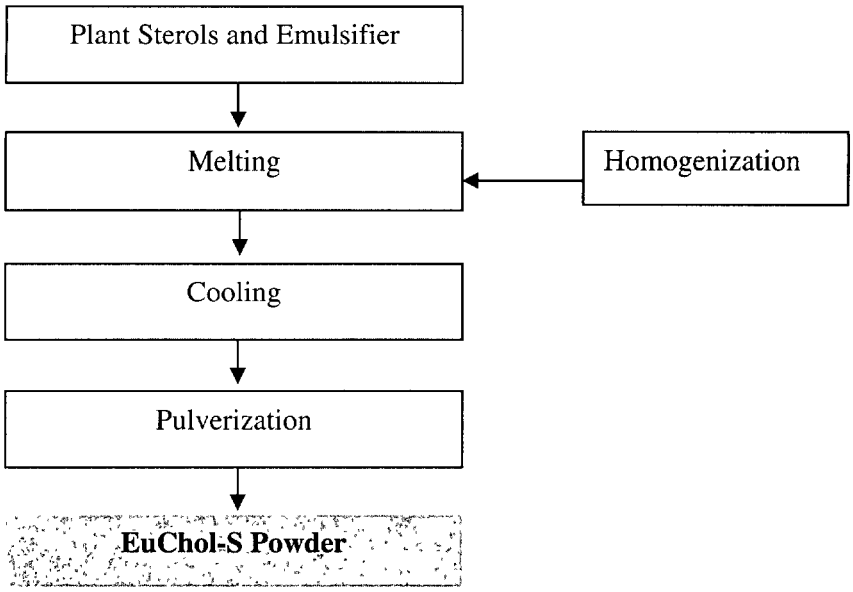
Euchol™-S

Euchol™-S is a phytosterol containing product developed by Eugene Science, a Korean biotech company. The product contains a blend of ADM phytosterols and sucrose fatty acid esters produced with Eugene Science's proprietary technology. The sucrose fatty acid esters are used to achieve the optimum emulsification of phytosterols in aqueous food applications. ADM has marketing rights of Euchol™-S in Europe and North America under the trade name of CardioAid™-WD Phytosterols.

Euchol™-S consists of about 50.0% phytosterols (CardioAid™ Phytosterols) and about 50.0% sucrose fatty acid esters. The manufacturing process includes mixing, melting with heat, cooking, pulverization, homogenization and packaging as shown in the *Figure 1* below.

The certificates of analysis from three batches and product specifications of Euchol™-S are shown in A*ppendix 2*. The product specifications and certificates of analysis from three batches of CardioAid™-WD are included in A*ppendix 3*.

Figure 1- Manufacturing Process of Euchol™-S



The sucrose fatty acid esters used in the manufacture of Euchol™-S meet the specifications of sucrose fatty acid esters set forth in 21CFR 172.859 of the U.S. food regulations and the Food Chemical Codex, 1977 (*Appendix 4*).

Regulatory status of sucrose fatty acid esters

In the United States, sucrose fatty acid esters may be used in the following food categories when established standards of identity do not preclude their use: 1) as an emulsifier or stabilizer in baked goods and baking mixes, chewing gum, coffee and tea beverages with added dairy ingredients, confections, frostings and dairy product analogues; 2) as texturizers in confections, frostings, and surimi based fabricated seafoods; and 3) as components of protective coatings applied to fresh fruits to retard ripening and spoiling (21CFR 172.859).

The U.S. FDA has written a no objection letter to Mitsubishi Chemical Company regarding their GRAS notification on sucrose fatty acid esters for use as an emulsifier in beta-carotene, beta-apo-8-carotenal (apocarotenal), and canthaxanthin color preparations when they are added to beverages, crackers, soups, and sauces. The maximum use level of sucrose fatty acid esters in these carotenoid color preparations is no more than 4 percent and a single food contains no more than one added carotenoid color preparation, (GRN 000129, November, 2003, *Appendix 5).*

Safety of sucrose fatty acid esters

Sucrose fatty acid esters have been considered safe by several regulatory bodies in Japan, Europe and North America. The Joint Food and Agriculture Organization/World Health Organization's Expert Committee on Food Additives (JECFA) has reviewed sucrose fatty acid esters on eight occasions since 1969, and most recently (1997) concluded that the data supports an acceptable daily intake of 30 milligrams per kilogram of body weight per day, which would correspond to 2.1 g per person per day for a 70 kilogram adult *(Appendix 6).*

In the European Union, sucrose esters of fatty acids (and sucroglycerides) were evaluated by the Scientific Committee for Food (SCF) in 1992. The SCF first established a group ADI of 0-20 mg/kg bw/day (expressed as sucrose monostearate) for sucrose esters of fatty acids and sucroglycerides derived from palm oil, lard and tallow fatty acids, provided that specifications would limit the presence of tetra or higher esters to no more than 7%. However, in 2002, the SCF was asked by the European Commission to re-evaluate the safety of sucrose esters of fatty acids in the light of new studies on short-and long-term toxicity in experimental animals as well as kinetic studies in animals and humans. This evaluation resulted in establishing a group ADI of 30 mg/kg bw/day for sucrose esters of fatty acids (E473) as reported in the EFSA Journal in 2004 *(Appendix 7)*. This ADI is similar to the one established by JECFA

The SCF also reported that sucrose esters of fatty acids have low oral toxicity and did not raise concerns about carcinogenicity, citing Takeda and Flood (2002). Yoshida, et. al, (2004) also reported lack of carcinogenicity in rats of S-170, a sucrose fatty acid mixture consisting of mainly tetra, penta, hexa and hepta fatty acid esters. Metabolic studies *in vitro* and in rats, dogs and humans show that these esters are: extensively hydrolyzed in the gastrointestinal tract into sucrose, stearic acid and palmitic acid prior to absorption; that only small amounts of intact monoesters which escape hydrolysis are absorbed; and that incompletely hydrolyzed sucrose esters appear to be excreted in the feces (Shigeoka et. al., 1984). There is no evidence of tissue accumulation of the absorbed monoesters. Studies using radio-labeled sucrose esters indicated that it is unlikely that di- and higher esters are absorbed intact (Noker et. al, 1997).

From the new 2-year chronic toxicity/carcinogenicity study, a NOAEL has been established at 5% sucrose esters of fatty acids in the diet of rats, equal to 1970 mg/kg bw/day in males and 2440 mg/kg bw/day in females (EFSA, 2004; *Appendix 7*). The test substances were composed of sucrose esters of stearic and palmitic acids (70:30) with a high content of tetra- and higher esters. The main effects seen in rats in previous long-term studies on sucrose esters of fatty acids containing lower levels of higher esters at very high doses (≥ 10% dietary levels) showed a tendency towards lower body weights, soft stool and diarrhea.

The metabolism in rats of sucrose fatty acid esters of stearic and palmitic acid have been studied *in vivo* and *in vitro* using esters labeled with ^{14}C at the sucrose or fatty acid moiety (Shigeoka et. al, 1984). Although sucrose fatty acid esters were hydrolyzed to sucrose and fatty acids prior to intestinal absorption, sucrose distearate was absorbed to a lesser extent than sucrose monostearate. The extent of absorption and metabolism of radioactivity of various sucrose esters were found to be inversely related to the degree of esterification (Noker et. al, 1997). The data also showed that radioactivity from the partially esterified sucrose tetrasterate was absorbed to a

greater extent than the more fully esterified molecules, sucrose hexastearate and sucrose octastearate.

Dietary exposure

In Europe, the Scientific Committee on Foods (2004) reported originally that conservative estimates of chronic intake of sucrose ester of fatty acids (E 473) and sucroglycerides (E 474) in the adult population were above 20 mg/kg bw/day at the 95th percentile (EFSA, 2004). Based on current maximum permitted levels, for a variety of foods and beverages, a single eating occasion would lead to intakes of sucrose esters of fatty acids (E 473) and sucroglycerides (E 474) in the range of 1 gram. High intakes on a one day basis could therefore be expected, particularly in children. Re-evaluation by EFSA of all existing safety data, taking into consideration both new rat studies and human tolerance studies, led to the establishment of an ADI for SFAE of 30 mg/kg bw/day (EFSA, 2004), *Appendix 7.*

ADM conducted the estimation of dietary intake of sucrose fatty acid ester from proposed food categories in U.S. population using the USDA Continuing Survey of Food Intakes by Individuals (CSFII) 1994-96, 98 database. The proposed food categories which include milk type products and fruit/vegetable juices are listed in *Appendix 8.*

Table 1 shows estimates of mean intake and 90th percentiles of the food servings and added sucrose fatty acid ester in "users" of U.S. population. When 0.4 gram of sucrose fatty acid esters is added to the proposed food categories, the estimated intakes are as follows.

1) Mean intake of sucrose fatty acid esters range from 7.7 mg/kg bw/day (in teenagers, age 12-19) to 13.5 mg/kg bw day (in children age 3-11). These estimated intakes are equivalent to the total daily consumption per person of 0.45 grams by teenagers, 0.96 grams by adults and 0.32 grams by children, age 3-11.

2) 90th percentile intake of sucrose fatty acid esters range from 16.4 mg/kg bw/day (in teenagers, age 12-19) to 26.2 mg/kg bw/day (in children age 3-11). These estimated intakes are equivalent to the total daily consumption per person of 1.15 grams by teenagers, 1.76 grams by adults, and 0.62 grams by children ages 3-11.

Table 1. Daily Intake levels of Food and SFAE from Proposed Food Categories*
(Based on USDA CSFII DATABASE 1994-98, in users only)
*Food included: fruit/vegetable juices and milk type products.
Contains up to 0.4 gram/per serving of SFAE and up to 0.4 gram/per serving of phytosterol

AGE	Label	N	Mean	90th Pctl
children 3-11	servings(person/day)	2913	0.8000	1.5563
	servings(kg BW/day)	2715	0.0339	0.0654
	grams(person/day)	2913	0.3200	0.6225
	grams(kg BW/day)	2715	0.0135	**0.0262**
teenagers 12-19	servings(person/day)	495	1.1202	2.0771
	servings(kg BW/day)	485	0.0193	0.0411
	grams(person/day)	495	0.4481	0.8308
	grams(kg BW/day)	485	0.0077	**0.0164**
adults 20 & over	servings(person/day)	3886	2.4076	4.5000
	servings(kg BW/day)	3818	0.0336	0.0639
	grams(person/day)	3886	0.9630	1.8000
	grams(kg BW/day)	3818	0.0134	**0.0256**

Potential adverse effects of sucrose fatty acid esters

Two human tolerance studies with sucrose esters of fatty acids (S-1170) are available (EFSA, 2004). In the first study, which had significant deficiencies, most notable in the limited size of the study groups and the lack of controls, it was reported that single doses of 1.5-3g S-1170, as well as repeated doses of 1–1.5g three times per day (3-4.5 g/day) for 5-7 days, administered in orange juice and bread, were associated with laxation and related abdominal symptoms. A divided dose of 2g per day for 5 days, equal to 33 mg/kg bw/day, produced no effect when administered in orange juice, and only a slight effect in 20% of persons when administered with bread. The highest dose tested, 4.5g per day, equal to 75 mg/kg bw/day, produced a range of gastrointestinal symptoms (soft stools, diarrhea, flatulence, borborygmus and a bloated sensation).

The second study employing 10 men and 10 women was well controlled. It used a double- blind, cross-over design and was conducted on an in-patient basis. Subjective symptoms and frequency and appearance of feces were recorded. Blood pressure, pulse, breathing rate, body temperature, body weight, and a standard set of clinical chemistry parameters were recorded prior to administration of the test substance and after the end of the treatment periods at day 7. Divided daily doses in bread of 1.5g for 5 days (equal to 27 mg/kg in men and 29 mg/kg in women) produced no adverse reactions. However, this was the only dose level tested, and it was lower than the dose range (33–75 mg/kg bw/day) reported to produce symptoms of laxation in the first study.

These human studies support the conclusion that ingestion of amounts above around 2 g/day in adults may give rise to gastrointestinal symptoms.

In a recent unpublished study, Shin et al, 2005 (Eugene Science internal report) evaluated the effects of micellar phytosterols on cholesterol absorption in humans using the Eucholᵀᴹ-S product. Twenty-four healthy adults (mean age: 37 years , 16 women and 8 men) underwent 4 cholesterol-absorption tests to compare the effects of micellar phytosterols supplement containing 500 mg, 300 mg, 200 mg phytosterols and placebo on cholesterol absorption in a cross-over design. These levels of phytosterols correspond to 500 mg, 300 mg and 200 mg of sucrose fatty acid esters. The cholesterol absorption for each dose treatment was measured four days after the administration of test. Individual absorption tests were separated by 2 weeks. They concluded that water-dispersible, micellar phytosterols reduced cholesterol absorption effectively at very low doses. No adverse effects, including laxation, were reported in this study. It is noted that the highest level of sucrose fatty acid esters of 500 mg is higher than the 400 mg estimated in the dietary intake.

Olestra is sometimes mistakenly confused with the mixture of sucrose fatty acid esters of this report. Olestra is not digestible, while the SFAE's used here are. Moreover, olestra is a mixture of octa-, hepta-, and hexa-esters of sucrose fatty acids whose chain lengths are no less than 12 carbon atoms. The total content of octa-, hepta-, and hexa-esters is not less than 97 percent (21 CFR 172.867). The SFAE's used here are mono, di and tri-esters.

Conclusion

The mean dietary intake estimate of sucrose fatty acid esters contained in 0.4 gram per serving of CardioAidᵀᴹ-WD phytosterol as used in fruit/vegetable juices and milk type products is estimated to range from 7.7 mg/kg bw/day (for teenagers, age 12-19) to 13.5mg/kg bw/day (for children, age 3-11). These estimated intakes are within the ADI of 0-30 mg/kg bw/day. These estimated intakes of sucrose fatty acid esters are equivalent to the total daily consumption per person of 0.45 grams by teenagers, 0.96 grams by adults and 0.32 grams by children, age 3-11. These total daily consumption values are less than the NOAEL of 2.0 gram per day.

The 90th percentile dietary intake estimate of sucrose fatty acid esters contained in 0.4 gram per serving of CardioAidᵀᴹ-WD phytosterol as used in fruit/vegetable juices and milk type products is estimated to range from 16.4 mg/kg bw/day (in teenagers, age 12-19) to 26.2 mg/kg bw/day (in children, age 3-11) . These estimated intakes of sucrose fatty acid esters are equivalent to the total daily consumption per person of 0.83 grams by teenagers, 1.80 grams by adults and 0.62 grams by children, age 3-11. These total daily consumption values are less than the ADI of 30 mg/kgBW/day and below the NOAEL of 2.0 gram per day. Even if we consider the addition of 1 mg/kg/day of cumulative intake of SFAE from all other sources, including its use as a food additive (GRAS Notice No.GRN 000129), the maximum 90th percentile intake becomes 27.2 mg/kgBW/day. This is equivalent to 1.63 g/day for a 60 kg reference person (27.2 x 60). Based on this analysis, the consumption of SFAE does not represent a safety concern.

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Appendices

Appendix 1 21 CFR 172.859, Sucrose Fatty Acid Esters.

Appendix 2 Certificates of analysis and product specifications of Euchol™-S.

Appendix 3 Product specifications and Certificates of analysis of CardioAid™-WD phytosterols.

Appendix 4 Food Chemical Codex on sucrose fatty acid esters.

Appendix 5 GRAS Notice No. GRN 000129. Sucrose fatty acid esters.

Appendix 6 JECFA Evaluation of Sucrose fatty acid esters.

Appendix 7 The EFSA Journal. Opinion of the Scientific Panel of Foods Additives ..... on sucrose fatty acid esters, E473 and sucroglycerides, E474 ....

Appendix 8 Food categories used to estimate the dietary intake of sucrose fatty acid esters.

Appendix 1

Appendix 1

21 CFR 172.859, Sucrose Fatty Acid Esters.

Pages 000152-000153 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Appendix 2

Appendix 2

Certificates of analysis and product specifications of

Euchol™-S Phytosterol powder

EUGENE SCIENCE

CERTIFICATE OF ANALYSIS

Sample Name: EuChol-S
Issue No.: ES-04-045
Issue Date: Jan. 10, 2005
Receipt Date: Aug. 06, 2004 Test Date: Aug. 12, 2004

TEST RESULTS

Test Item	Specification	Result
Appearance	Light yellow power	Pass
Total Phytosterol	Min. 47.0%	49.19%
Loss and drying	Max. 1.0%	0.68%
Residue of Ignition	Max. 1.0%	0.68%
Heavy metals	Max. 10ppm	Pass
Arsenic	Max. 4ppm	Pass
Viable cell count	Less than 300/g	Negative
Coliform group	Negative	Negative
Bacillus coil	Negative	Negative
Salmonella	Negative	Negative
Staphylococcus aureus	Negative	Negative
Heat stable Spore		
-Aerobic	Negative	Negative
-Anaerobic	Negative	Negative
-Acidophilic	Negative	Negative
Water dispersion ability	Pass	Pass

Usage: Phytosterol analysis

Note: 1. This test report shall not be used outside the purpose of its defined usage.
2. The results have been made for the sample presented by the client.

Testing Personnel: Young-MI Lee (b) (6)
Approval Staff: Jang-Hyun Cho, PH.D.
Chief Research Scienetist
Quality Assurance Dept.
Eugene Science, Ltd.

BEST ORIGINAL COPY

16-7, Samjung-dong, Ojung-Gu, Bucheon, Kyonggi-Do, Korea, 421-150
Tel: 82-2-338-6284/Fax: 82-2-338-9450

EUGENE SCIENCE

CERTIFICATE OF ANALYSIS

Sample Name: EuChol-S
Issue No.: ES-04-029
Issue Date: Jan. 10, 2005
Receipt Date: May. 07. 2004 Test Date: May. 12. 2004

TEST RESULTS

Test Item	Specification	Result
Appearance	Light yellow power	Pass
Total Phytosterol	Min. 47.0%	48.03%
Loss and drying	Max. 1.0%	0.42%
Residue of Ignition	Max. 1.0%	0.08%
Heavy metals	Max. 10ppm	Pass
Arsenic	Max. 4ppm	Pass
Viable cell count	Less than 300/g	Negative
Coliform group	Negative	Negative
Bacillus coli	Negative	Negative
Salmonella	Negative	Negative
Staphylococcus aureus	Negative	Negative
Heat stable Spore		
-Aerobic	Negative	Negative
-Anaerobic	Negative	Negative
-Acidophilic	Negative	Negative
Water dispersion ability	Pass	Pass

Usage: *Phytosterol analysis*

Note: 1. This test report shall not be used outside the purpose of its defined usage.
2. The results have been made for the sample presented by the client.

Testing Personnel: Young-Mi Lee (b) [redacted]
Approval Staff: Jang-Hyun Cho, PH.D.
Chief Research Scienetist
Quality Assurance Dept.
Eugene Science, Ltd.

BEST ORIGINAL COPY

16-7, Samjung-dong, Ojung-Gu, Bucheon, Kyonggi-Do, Korea, 421-150
Tel: 82-2-338-6284/Fax: 82-2-338-9450

EUGENE SCIENCE

CERTIFICATE OF ANALYSIS

Sample Name: EuChol-S
Issue No.: EPD-0412
Issue Date: Jan. 10, 2005
Receipt Date: Dec. 17, 2004 Test Date: Dec. 18, 2004

TEST RESULTS

Test Item	Specification	Result
Appearance	Light yellow power	Pass
Total Phytosterol	Min. 47.0%	49.04%
Loss and drying	Max. 1.0%	0.69%
Residue of ignition	Max. 1.0%	0.42%
Heavy metals	Max. 10ppm	Pass
Arsenic	Max. 4ppm	Pass
Viable cell count	Less than 300/g	Negative
Coliform group	Negative	Negative
Bacillus coli	Negative	Negative
Salmonella	Negative	Negative
Staphylococcus aureus	Negative	Negative
Heat stable Spore		
-Aerobic	Negative	Negative
-Anaerobic	Negative	Negative
-Acidophilic	Negative	Negative
Water dispersion ability	Pass	Pass

Usage: Phytosterol analysis

Note: 1. This test report shall not be used outside the purpose of its defined usage.
2. The results have been made for the sample presented by the client.

Testing Personnel: Ju-Hee Choi, Jung-Hoon Lee
Approval Staff: Jang-Hyun Cho, PH.D. (b) [redacted]
Chief Research Scienetist
Quality Assurance Dept.
Eugene Science, Ltd.

BEST ORIGINAL COPY

16-7, Samjung-dong, Ojung-Gu, Bucheon, Kyonggi-Do, Korea, 421-150
Tel: 82-2-338-6284/Fax: 82-2-338-9450

3) Certificate of Analysis

SPECIFICATION

Product Name: EuChol-S

Item	Specification
Appearance	Light Yellow Powder
Assay (total phytosterol)	Min. 47.0%
Loss on Drying	Max. 1.0%
Residue of Ignition	Max. 1.0%
Heavy metals	Max. 10 ppm
Arsenic	Max. 4 ppm
Viable cell count	Less than 300/g
Coliform group	Negative
Bacillus coli	Negative
Salmonella	Negative
Staphylococcus aureus	Negative
Heat stable Spore	
Aerobic	Negative
Anaerobic	Negative
Acidophilic	Negative
Water dispersion ability	Pass

4) **MSDS of EuChol™-S**

MATERIAL SAFETY DATA SHEET

1. PRODUCT & COMPANY IDENTIFICATION

PRODUCT NAME (USED ON LABEL) **EuChol™-S**

NAME OF MANUFACTURER

Eugene Science

16-7, Samjung-Dong, Ojung-Gu, Bucheon, Kyonggi-Do, Korea

TELEPHONE +82-32-676-6283

FACSIMILE +82-32-676-6373

2. COMPOSITION/INFORMATION ON INGREDIENTS

SUBSTANCE/MIXTURE	MIXTURE	
CHEMICAL NAME	CAS REGISTRY NUMBER	EINECS NUMBER
Plant sterols		
β-sitosterol	83-46-5	201-480-6
Campesterol	474-62-4	207-484-7
Stigmasterol	83-48-7	201-482-7
Other sterols		
Sucrose fatty acid esters		
Sucrose monostearate	25168-73-4	246-705-9
Sucrose distearate	27195-16-0	248-317-5
Sucrose monopalmitate	26446-38-8	247-706-7
Sucrose dipalmitate	25637-97-2	247-147-9
Sucrose alkylate		
Total	more than 98% (other: Ash, Moisture)	

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Dust explosive. Control dust concentration or make O_2 concentration lower and keep away from any source of ignition including electrostatic sparks.

POTENTIAL HEALTH EFFECTS

000159

EYE CONTACT: May cause slight irritation

SKIN CONTACT: May cause slight irritation

INHALATION: Not available (May cause slight irritation)

4. FIRST-AID MEASURES

EYE CONTACT

Do not allow victim to rub or keep eyes tightly shut. Gently lift eyelids and flush immediately and continuously with flooding amounts of clean water for 15 minutes. If irritation persists, seek professional medical assistance.

SKIN CONTACT

Wash the affected area under tepid running water.

INGESTION

Rinse mouth and dilute with water.

INHALATION

Remove exposed person to fresh air and assist breathing as necessary.

5. FIRE-FIGHTING MEASURES

EXTINGUISH MEDIA CO_2, Dry chemical, foam or water fog.

FIRE-FIGHTING PROCEDURE

Fire-fighters should wear full protective clothing including a self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURE

Keep unnecessary people away, isolate hazard area and deny entry. Do not walk through spilled material.

With a clean shovel place material into clean, dry container and cover loosely.

Move containers from spill area for later disposal.

7. HANDLING & STORAGE

Avoid humid and hot atmosphere for quality control. Eliminate any source of ignition. Keep containers close to avoid dust scattering and contamination. Store in a cool, dark, well-ventilated space. Keep the container tightly closed while not in use. Provide ventilation when using.

8. EXPOSURE CONTROL/PERSONAL PROTECTION

EXPOSURE LIMITS	Not established
PERSONAL PROTECTION	
EYE PROTECTION :	Safety goggles
HAND PROTECTION :	Gloves
INHALATION PROTECTION :	Dust mask

ENGINEERING CONTROLLS

VENTILATION

Use general or local exhaust ventilation, or other engineering controls to control airborne dust levels. If dust is generated during use, extinguish all ignition sources including electrostatic sources.

Appendix 3

000161.001

Appendix 3

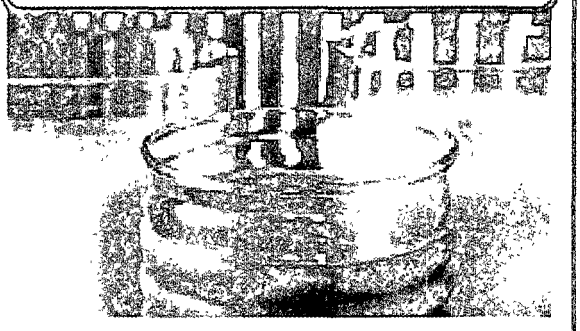
Product specifications and certificates of analysis of

CardioAid™-WD phytosterols

CardioAid™-WD Phytosterols

ADM Product Code 040560
Technical Data Sheet

CardioAid



Description

CardioAid™-WD phytosterols are a light cream-colored powder with a slight odor and taste. This phytosterols-sucrose fatty acid esters complex is formulated for use in beverages and other aqueous-based systems.

The phytosterols of CardioAid-WD are derived from vegetable oils. Structurally similar to cholesterol, phytosterols have been found, in studies, to reduce the absorption of dietary cholesterol, which can impact serum cholesterol levels. [Mayo Clin Proc 78:965-78 (2003); AJCN 74:33-43 (2001)].

The FDA will allow the following claim for products containing phytosterols like CardioAid-WD: Foods containing at least 0.4 gram per serving of plant sterols, eaten twice a day with meals for a daily total intake of at least 0.8 gram, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of the food] supplies ____ gram(s) of plant sterols.

Typical Chemical and Physical Properties

Phytosterol	
Total phytosterols	47.0
Beta-sitosterol	40-58*
Campesterol	20-30*
Stigmasterol	14-22*
Brassicasterol	0-6*
Sitostanol	0-5*
Appearance	Fine powder
Odor	Slight
Tocopherols	0-15 mg/g
Heavy metals	Maximum 10 ppm
Solubility in water	Dispersible

Ingredients List

Plant sterols and sucrose fatty acid esters.

*As percent of total sterols

Storage and Shelf Life

CardioAid-WD phytosterols should be stored in closed packaging under dry conditions. When stored in unopened original packing and under recommended storage conditions, the shelf life is 18 months.

Packaging and Product Codes

10 kg bag (ADM Code 040560)

PS-007-040609

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The information contained herein is correct to the best of our knowledge. The recommendations or suggestions contained in this bulletin are made without guarantee or representation as to results. We suggest that you evaluate these recommendations and suggestions in your own laboratory prior to use. Our responsibility for claims arising from breach of warranty, negligence or otherwise is limited to the purchase price of the material. Freedom to use any patent owned by ADM or others is not to be inferred from any statement contained herein.

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ADM

Natural ingredients to promote health and well-being, custom formulated for any food or supplement. THE NATURE OF WHAT'S TO COME™

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CardioAid™-WD Phytosterols

ADM product code 040560

Technical Data Sheet

Description:

CardioAid™-WD Phytosterols is light cream powder having a slight odor and taste. CardioAid ™-WD is a phytosterols-sucrose fatty acid esters complex formulated for use in beverages and other aqueous-based systems.

The Phytosterols of CardioAid ™-WD are derived from vegetable oils. Structurally similar to cholesterol, phytosterols have been found, in studies, to reduce the absorption of dietary cholesterol which can impact serum cholesterol levels. [J. of Nutr., 107:1139-1146 (1977); Can. J. Physiol. Pharmacol., 75:217-227(1997)].

The FDA has allowed the following claim, for products containing CardioAid™-WD: "***Foods containing at least 0.4 gram per serving of plant sterols, eaten twice a day with meals for a daily total intake of at least 0.8 gram, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of the food] supplies ____ gram(s) of plant sterol.***"

Typical Chemical and Physical Properties

Appearance:	Fine powder
Odor	Slight
Total phytosterols	47.0 % minimum
Beta-sitosterol (% of total sterols)	80% maximum
Beta-sitostanol (% of total sterols)	15% maximum
Campesterol (% of total sterols)	40% maximum
Campestanol (% of total sterols)	5% maximum
Stigmasterol (% of total sterols)	30% maximum
Brassicasterol (% of total sterols)	3% maximum
Other sterols and stanol s (% of total sterols)	3% maximum
Tocopherols	0 - 15 mg/g
Heavy Metals	10 ppm maximum
Solubility in water	Dispersible

Ingredients list

Plant sterols and sucrose fatty acid esters.

Storage and Shelf-Life

CardioAid™-WD should be stored in closed packaging under dry conditions. When stored in unopened original packing and under recommended storage conditions, the shelf life is 18 months.

Packaging and Product Codes

10 kg bag (ADM Code 040560)

PS-007-040609

The information contained herein is correct to the best of our knowledge. The recommendations or suggestions contained in this data sheet are made without guarantee or representation as to results. We suggest that you evaluate these recommendations and suggestions in your own laboratory prior to use. Our responsibility for claims arising from breach of warranty, negligence, or otherwise is limited to the purchase price of the material. Freedom to use any patent owned by ADM or others is not to be inferred from any statement contained herein.

RUN-DATE: 08/25/04
RUN-TIME: 11:13:01

ADM PROCESSING - NUTRACEUTICALS
3700 EAST DIVISION

DECATUR IL 62526

** SHIPTO **

```
*****************************
*** ARCHER DANIELS MIDLAND ***
***      CERTIFICATE      ***
***      OF ANALYSIS      ***
*****************************
```

* CUSTOMER PO# ADM ORDNO # *INVOICE # 1034
PRODUCT CD: 040560 CUSTOMER PRODUCT CD:
PRODUCT DESC:CARDIOAID-WD (WATER DISPERSABLE)
LOTNO: EXP0604009 TEST DATE: 06/09/04 DATE OF EXPIRY: 11/05/05
SHIP DATE: / / CARNO:
SHIP FROM: DECATUR ,IL
MANUFACTURE DATE: 05/07/04
QTY 1 NET WEIGHT 25.000 K
CONTAINER CD: 5K 25K F DR

TEST	ASSAY RESULTS
LAB NUMBER	604009
TOTAL STEROLS (TS)	50.8 %
CHOLESTEROL (%TS)	0.4 %
BRASSICASTEROL (%TS)	1.6 %
CAMPESTEROL (%TS)	25.8 %
CAMPESTANOL (%TS)	1.2 %
STIGMASTEROL (%TS)	21.8 %
SITOSTEROL (%TS)	44.7 %
SITOSTANOL (%TS)	1.8 %
OTHER STEROLS (%TS)	2.7 %

*
THIS PRODUCT IS TESTED PERIODICALLY TO ENSURE IT MEETS THE FOLLOWING CRITERIA:
HEAVY METALS < 10 PPM, LEAD < 2 PPM
OVI CONTENT COMPLIES WITH USP STANDARDS
*

CHRIS SCHUETTE

QC MANAGER

(b) [redacted]

RUN-DATE: 08/25/04
RUN-TIME: 11:28:30

ADM PROCESSING - NUTRACEUTICALS
3700 EAST DIVISION

DECATUR IL 62526

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*****************************
*** ARCHER DANIELS MIDLAND ***
***      CERTIFICATE      ***
***      OF ANALYSIS      ***
*****************************
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SHIPTO *

* CUSTOMER PO# ADM ORDNO # *INVOICE # 1034
PRODUCT CD: 040560 CUSTOMER PRODUCT CD:
PRODUCT DESC:CARDIOAID-WD (WATER DISPERSABLE)
LOTNO: EXP0704013 TEST DATE: 08/03/04 DATE OF EXPIRY: 11/05/05
SHIP DATE: / / CARNO:
SHIP FROM: DECATUR ,IL
MANUFACTURE DATE: 05/07/04
QTY 1 NET WEIGHT 25.000 K
CONTAINER CD: 5K 25K F DR

TEST	ASSAY RESULTS
LAB NUMBER	704013
TOTAL STEROLS (TS)	53.1 %
CHOLESTEROL (%TS)	0.4 %
BRASSICASTEROL (%TS)	1.5 %
CAMPESTEROL (%TS)	25.6 %
CAMPESTANOL (%TS)	0.7 %
STIGMASTEROL (%TS)	21.9 %
SITOSTEROL (%TS)	45.4 %
SITOSTANOL (%TS)	1.9 %
OTHER STEROLS (%TS)	2.6 %

*
THIS PRODUCT IS TESTED PERIODICALLY TO ENSURE IT MEETS THE FOLLOWING CRITERIA:
HEAVY METALS < 10 PPM, LEAD < 2 PPM
OVI CONTENT COMPLIES WITH USP STANDARDS
*

CHRIS SCHUETTE

QC MANAGER

(b)

RUN-DATE: 08/25/04
RUN-TIME: 11:11:19

ADM PROCESSING - NUTRACEUTICALS
3700 EAST DIVISION

DECATUR IL 62526

** SHIPTO **

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*****************************
*** ARCHER DANIELS MIDLAND ***
***      CERTIFICATE      ***
***      OF ANALYSIS      ***
*****************************
```

* CUSTOMER PO# ADM ORDNO # *INVOICE # 1034
PRODUCT CD: 040560 CUSTOMER PRODUCT CD:
PRODUCT DESC:CARDIOAID-WD (WATER DISPERSABLE)
LOTNO: EXP0804025 TEST DATE: 08/23/04 DATE OF EXPIRY: 02/04/06
SHIP DATE: / / CARNO:
SHIP FROM: DECATUR ,IL
MANUFACTURE DATE: 08/06/04
QTY 1 NET WEIGHT 25.000 K
CONTAINER CD: 5K 25K F DR

TEST	ASSAY RESULTS	
LAB NUMBER	804025	
TOTAL STEROLS (TS)	49.6	%
CHOLESTEROL (%TS)	0.4	%
BRASSICASTEROL (%TS)	1.4	%
CAMPESTEROL (%TS)	27.0	%
CAMPESTANOL (%TS)	0.8	%
STIGMASTEROL (%TS)	22.2	%
SITOSTEROL (%TS)	44.4	%
SITOSTANOL (%TS)	1.6	%
OTHER STEROLS (%TS)	2.2	%

*
THIS PRODUCT IS TESTED PERIODICALLY TO ENSURE IT MEETS THE FOLLOWING CRITERIA:
HEAVY METALS < 10 PPM, LEAD < 2 PPM
OVI CONTENT COMPLIES WITH USP STANDARDS
•

CHRIS SCHUETTE

QC MANAGER

(b)

Appendix H

Appendix 4

Food Chemical Codex on sucrose fatty acid esters

Pages 000169-000171 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Appendix 5

000171.001

Appendix 5

GRAS Notice No. GRN 000129.

Sucrose fatty acid esters

CFSAN/Office of Food Additive Safety
November 7, 2003

Agency Response Letter
GRAS Notice No. GRN 000129

John S. Eldred
Keller and Heckman, LLP
1001 G Street, N.W.
Washington, D.C. 20001

Re: GRAS Notice No. GRN 000129

Dear Mr. Eldred:

The Food and Drug Administration (FDA) is responding to the notice, dated May 15, 2003, that you submitted on behalf of Mitsubishi Chemical Corporation (Mitsubishi) in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received the notice on May 19, 2003, filed it on May 21, 2003, and designated it as GRAS Notice No. GRN 000129.

The subject of the notice is sucrose fatty acid esters (SFAE). The notice informs FDA of the view of Mitsubishi that SFAE are GRAS, through scientific procedures, for use as an emulsifier in beta-carotene, beta-apo-8-carotenal (apocarotenal), and canthaxanthin color preparations when they are added to beverages, crackers, soups, and sauces. Mitsubishi states that the maximum use level of SFAE in these carotenoid color preparations will be no more than 4 percent and a single food will contain no more than one added carotenoid color preparation.

Mitsubishi previously informed FDA of its view that SFAE are GRAS, through scientific procedures, for use as an emulsifier in beta-carotene color preparations intended for use in orange colored beverages such as soft drinks and juices at a level not more than 2 percent of the beta-carotene color preparation. FDA received this earlier notice on December 6, 2001, filed it on December 12, 2001, and designated it as GRAS Notice No. GRN 000092. FDA responded on February 4, 2002, stating that GRAS Notice No. GRN 000092 did not provide a basis to conclude that SFAE were GRAS for their intended use. In its letter, FDA explained that data and information cited by Mitsubishi in support of the GRAS determination were not generally available to the expert scientific community and thus did not satisfy common knowledge elements required for GRAS status. In GRAS Notice No. GRN 000129, Mitsubishi has provided additional published data and information that were not generally available at the time GRAS Notice No. GRN 000092 was submitted.

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Mitsubishi describes SFAE as a grayish white powder, stiff gel or soft solid. SFAE are a mixture of mono-, di-, and tri-esters of sucrose with fatty acids that are derived from edible vegetable or hydrogenated edible vegetable oils and fats. SFAE are manufactured by inter-esterification of sucrose with methyl esters of fatty acids in the presence of food-grade solvents and comply with the specifications in the Food Chemicals Codex, Fourth Edition, First Supplement (1997).

Mitsubishi describes published studies relating to the absorption, distribution, metabolism and excretion (ADME) of SFAE in humans. Mitsubishi concludes that these studies demonstrate that pancreatic lipase in the small intestine completely converts SFAE to sucrose and fatty acids prior to absorption. Mitsubishi describes other published studies conducted with SFAE, including a subchronic 13-week rodent feeding study and a two-year chronic toxicity rodent feeding study. Mitsubishi reports that there were no observed treatment-related adverse effects in either the 13-week study or two-year study.

Mitsubishi reports that SFAE have been considered to be safe by several regulatory bodies in Japan, Europe and North America. The Joint Food and Agriculture Organization/World Health Organization's Expert Committee on Food Additives (JECFA) has reviewed SFAE on eight occasions and most recently concluded that the data supports an acceptable daily intake of 30 milligrams per kilogram of body weight per day, which would correspond to 1800 milligrams per person per day (mg/person/day) for a 60 kilogram adult. FDA has approved SFAE as a food additive for use as an emulsifier, stabilizer, and texturizer in multiple food categories (21 CFR 172.859).[1]

Mitsubishi estimates that its use of SFAE would result in the consumption of approximately 8 mg/person/day at the 90th percentile of intake and that the cumulative exposure to SFAE arising from all uses in the U.S. would be no more than 60 mg/person/day.

Based on the information provided by Mitsubishi, as well as other information available to FDA, the agency has no questions at this time regarding Mitsubishi's conclusion that SFAE are GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of SFAE. As always, it is the continuing responsibility of Mitsubishi to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in Mitsubishi's notice that conforms to the information proposed in 21 CFR 170.36(c)(1), is available for public review and copying on the homepage of the Office of Food Additive Safety (on the Internet at http://www.cfsan.fda.gov/~lrd/foodadd.html).

Sincerely,
/s/
Laura M. Tarantino, Ph.D.
Acting Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

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(1)Mitsubishi notes that the specifications for the SFAE that are the subject of its notice comply with the specifications for SFAE that are currently in 21 CFR 172.859 as well as with the specifications for SFAE that are in the Food Chemicals Codex, Fourth Edition, First Supplement (1997).

GR

Appendix 6

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Appendix 6

JECFA Evaluation of Sucrose fatty acid esters

Pages 000177-000194 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Appendix 7

000194.001

Appendix 7

The EFSA Journal. Opinion of the Scientific Panel of Foods Additives . . .

on sucrose fatty acid esters, E473 and sucroglycerides, E474 . . .

Pages 000196-000218 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Appendix 8

000218.001

Appendix 8

Food categories for estimating dietary intake of sucrose fatty acid esters

1. USDA Food Codes and Names for Milk Type Products

Food code	Food name
11211050	Milk, evaporated, whole, NS as to dilution, used in coffee or tea
11212050	Milk, evaporated, skim, NS as to dilution, used in coffee or tea
11213050	Milk, evaporated, filled with vegetable oil, NS as to dilution, used in coffee or tea
11310000	Milk, imitation, fluid, soy based
11320000	Milk, soy, ready-to-drink, not baby's
11330000	Milk, soy, dry, reconstituted, not baby's
11514300	Cocoa with nonfat dry milk and low calorie sweetener, mixture, water added
11515400	Cocoa with nonfat dry milk and low calorie sweetener, high calcium, water added
11516000	Cocoa, whey, and low-calorie sweetener mixture, lowfat milk added
11518000	Milk beverage with nonfat dry milk and low calorie sweetener, water added, chocolate
11518050	Milk beverage with nonfat dry milk and low calorie sweetener, water added, flavors other than chocolate
11518100	Milk beverage with nonfat dry milk and low calorie sweetener, high calcium, water added, chocolate
11552200	Milk-based fruit drink
11553000	Fruit smoothie drink, made with fruit or fruit juice and dairy products
11553100	Fruit smoothie drink, NFS
11560000	Chocolate-flavored drink, whey- and milk-based
11560020	Flavored milk drink, whey- and milk-based, flavors other than chocolate
11560100	Flavored milk drink, skim milk and cream-based, flavors other than chocolate
11560110	Chocolate-flavored milk drink, skim milk and cream-based
11611000	Instant breakfast, fluid, canned
11612000	Instant breakfast, powder, milk added
11613000	Instant breakfast, powder, sweetened with low calorie sweetener, milk added
11621000	Diet beverage, liquid, canned
11622000	Diet beverage, powder, milk added
11622010	Diet beverage, powder, reconstituted with skim milk
11623000	Meal supplement or replacement, commercially prepared, ready-to-drink
11631000	High calorie beverage, canned or powdered, reconstituted
11641000	Meal supplement or replacement, milk-based, high protein, liquid
11651010	Meal replacement formula, Cambridge diet, reconstituted, all flavors
11830100	Cocoa (or chocolate) with dry milk and sugar, dry mix, not reconstituted
11830110	Cocoa powder with nonfat dry milk and low calorie sweetener, dry mix, not reconstituted
11830120	Cocoa, whey, and low calorie sweetener, fortified, dry mix, not reconstituted
11830140	Chocolate, instant, dry mix, fortified with vitamins and minerals, not reconstituted, Puerto Rican style
11830150	Cocoa powder, not reconstituted (no dry milk)
11830160	Cocoa (or chocolate) flavored beverage powder with sugar, dry mix, not reconstituted
11830170	Cocoa, whey, and low-calorie sweetener mixture, not reconstituted
11830180	Cocoa (or chocolate) flavored beverage powder with low calorie sweetener, dry mix, not reconstituted
11830500	Milk beverage, powder, with nonfat dry milk and low calorie sweetener, dry mix, not reconstituted, chocolate
11830550	Milk beverage, powder, with nonfat dry milk and low calorie sweetener, dry mix, not reconstituted, flavors other than chocolate
11830800	Instant breakfast, powder, not reconstituted
11830810	Instant breakfast, powder, sweetened with low calorie sweetener, not reconstituted
11830850	High calorie milk beverage, powder, not reconstituted
11830900	Protein supplement, milk-based, powdered, not reconstituted
11830940	Meal replacement, high protein, milk based, fruit juice mixable formula, powdered, not reconstituted
11830950	Nutrient supplement, milk-based, powdered, not reconstituted
11830960	Protein supplement, milk-based, sodium controlled, powdered, not reconstituted
11830970	Meal replacement, protein type, milk-based, powdered, not reconstituted

11830980	Protein supplement, milk-based, powdered, not reconstituted
11830990	Nutrient supplement, milk-based, powdered, not reconstituted
11831500	Nutrient supplement, milk-based, high protein, powdered, not reconstituted
11832000	Meal replacement, protein type, milk- and soy-based, powdered, not reconstituted
11832500	Meal replacement, protein type, milk-based, with sugar and artificial sweetener, not reconstituted
11835000	Meal replacement or nutritional supplement, Cambridge diet formula, powdered, nonfat milk solids base, dry, not recon- stituted
11835100	Meal replacement, Amway's Nutrilite brand Positnm Dnnk Mix, powdered nonfat dry milk-based, dry, not reconstituted
12200100	Cream substitute, liquid or powder
12210200	Cream substitute, liquid
12210250	Cream substitute, light, liquid
12210400	Cream substitute, powder
12210410	Cream substitute, light, powder

2. USDA Food Codes and Names for Fruit and vegetable Juice

Food code	Food name
61201000	Grapefruit juice, NFS
61201020	Grapefruit juice, unsweetened, NS as to form
61201220	Grapefruit juice, canned, bottled or in a carton, unsweetened
61201230	Grapefruit juice, canned, bottled or in a carton, with sugar
61201240	Grapefruit juice, canned, bottled, or in a carton, sweetened with low calorie sweetener
61201620	Grapefruit juice, frozen, unsweetened (reconstituted with water)
61201630	Grapefruit juice, frozen, with sugar (reconstituted with water)
61210000	Orange juice, NFS
61210220	Orange juice, canned, bottled or in a carton, unsweetened
61210230	Orange juice, canned, bottled or in a carton, with sugar
61210250	Orange juice, with calcium added, canned, bottled or in a carton, unsweetened
61210620	Orange juice, frozen, unsweetened (reconstituted with water)
61210630	Orange juice, frozen, with sugar (reconstituted with water)
61210720	Orange juice, frozen, unsweetened, not reconstituted
61210730	Orange juice, frozen, with sugar, not reconstituted
61210820	Orange juice, frozen, with calcium added (reconstituted with water)
61213000	Tangerine juice, NFS
61213220	Tangerine juice, canned, unsweetened
61213230	Tangerine juice, canned, with sugar
61213620	Tangerine juice, frozen, unsweetened (reconstituted with water)
61214000	Grape-tangerine-lemon juice
61216000	Grapefruit and orange juice, NFS
61216220	Grapefruit and orange juice, canned, unsweetened
61216230	Grapefruit and orange juice, canned, with sugar
61216620	Grapefruit and orange juice, frozen (reconstituted with water)
61219000	Orange and banana juice
61219100	Pineapple-orange-banana juice
61219150	Orange-white grape-peach juice
61219650	Apricot-orange juice
61222000	Pineapple-grapefruit juice, NFS

61222200	Pineapple-grapefruit juice, canned, bottled or in a carton, NS as to sweetened or unsweetened
61222220	Pineapple-grapefruit juice, canned, bottled or in a carton, unsweetened
61222230	Pineapple-grapefruit juice, canned, bottled or in a carton, with sugar
61222600	Pineapple-grapefruit juice, frozen (reconstituted with water)
61225000	Pineapple-orange juice, NFS
61225200	Pineapple-orange juice, canned, NS as to sweetened or unsweetened; sweetened, NS as to type of sweetener
61225220	Pineapple-orange juice, canned, unsweetened
61225230	Pineapple-orange juice, canned, with sugar
61225600	Pineapple-orange juice, frozen (reconstituted with water)
64100100	Fruit juice, NFS
64100110	Fruit juice blend, 100% juice, with added Vitamin C
64104600	Blackberry juice
64105400	Cranberry juice, unsweetened
64105500	Cranberry-white grape juice mixture, unsweetened
64116010	Grape juice, NS as to added sweetener
64116020	Grape juice, unsweetened
64116030	Grape juice, with sugar
64116040	Grape juice, low-calorie sweetener
64116050	Grape juice, NS as to sweetened or unsweetened, with added vitamin C
64116100	Grape juice, unsweetened, with added vitamin C
64116150	Grape juice, with sugar, with added vitamin C
64120010	Papaya juice
64121000	Passion fruit juice
64122030	Peach juice, with sugar
64124010	Pineapple juice, NS as to sweetened or unsweetened
64124020	Pineapple juice, unsweetened
64124030	Pineapple juice, with sugar
64124060	Pineapple juice, unsweetened, with added Vitamin C
64124200	Pineapple-apple-guava juice, with added vitamin C
64125000	Pineapple juice-non-citrus juice blend, unsweetened, with added vitamin C
64132010	Prune juice, NS as to added sweetener
64132020	Prune juice, unsweetened
64132030	Prune juice, with sugar
74301150	Tomato juice, low sodium
74302000	Tomato juice cocktail
74303000	Tomato and vegetable juice, mostly tomato
74303100	Tomato and vegetable juice, mostly tomato, low sodium
74304000	Tomato juice with clam or beef juice

Appendix I

000222.001

Appendix I

ADM Expert GRAS Panel Report. Opinion of an expert panel concerning the generally recognized as safe (GRAS) status of phytosterols applied to an expanded range of food categories (June 9, 2005)

OPINION OF AN EXPERT PANEL CONCERNING THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF PHYTOSTEROLS APPLIED TO AN EXPANDED RANGE OF FOOD CATEGORIES

(Sterols and Sterol Esters derived from either edible vegetable oils or tall oil)

Panel Members:

Joseph F. Borzelleca, Ph.D.

Walter H. Glinsmann, M.D.

David Kritchevsky, Ph.D.

Michael Pariza, Ph.D.

Prepared for

Archer Daniels Midland Company

June 9, 2005

000224

000224

Introduction

An independent panel of recognized experts qualified by relevant national and international experience and scientific training to evaluate the safety of food ingredients (herein referred to as Expert Panel or Panel) was requested by Archer Daniels Midland Company (ADM) to investigate the Generally Recognized As Safe (GRAS) status of plant sterols and plant sterol esters, derived from either edible vegetable oil or tall oil (wood sterols), as applied to an expanded range of food categories, some of which require the use of Sucrose Fatty Acid Esters as emulsifier.

The panel independently and collectively critically evaluated a comprehensive package of publicly available scientific and regulatory information and data compiled by ADM into a dossier. The panel also reviewed additional information deemed appropriate. This dossier was then modified by Panel members and reviewed in final form. Following critical evaluation of the information and data, the Panel was asked to render an opinion on whether ADM products meeting food grade specifications and manufactured in compliance with current Good Manufacturing Practices (c-GMP) are GRAS for their intended use.

Background

The safe use and health benefits of plant sterols and plant sterol esters has been well documented (1). Historically, sterols were first introduced in the U.S. and Canadian markets in the 1950's as a cholesterol lowering drug under the name of Cytellin (Eli Lilly). It stayed in the market for 29 years and it was discontinued due to the development of statin drugs. Therapeutic levels of Cytellin ranged from 9-30g/day and repeated clinical investigations reported no contraindications or side effects (2-4). More recently, the introduction in the market of functional foods containing phytosterols has contributed to the human exposure of sterols beyond levels naturally occurring in the diet. However, the safety of this increased dietary consumption has been thoroughly evaluated by scientists and health authorities in various countries, primarily in Europe and in the United States. As a result, since 1999 a series of market authorizations for the use of plant sterol and plant sterol esters have been granted to several companies in Europe and the United States for their use in a broad range of food categories. In the U.S., since 1999 the FDA has been notified by various food companies about the regulatory self-determined Generally Recognized As Safe (GRAS) status for the use of plant sterol and plant sterol esters in products such as vegetable oil spreads (Lipton/Unilever, FDA letter from A.M. Rulis to D. Dwyer, 4/30/99; Novartis Consumer Health, Inc. GRN 000039, 4/24/00); vegetable oils (The Procter and Gamble Company, GRN 000053, 12/20/00); vegetable oil spreads, dressing for salads, bars and yogurt (Cargill Incorporated, GRN 000048, 11/27/00) and of vegetable oil spreads, dressing for salads, health drinks, health bars and yogurt-type products (Archer Daniels Midland Company, GRN 000061, 4/18/2001). More recently, on February 4, 2003, Teriaka, Ltd. gained self-affirmed GRAS status of an even wider range of products than those listed in the above notifications, by including beverages, ice cream, cheese and cream cheese-like products, snack bars, mayonnaise and some types of bread (Teriaka, Ltd., GRN 000112, 2/4/03).

In addition to the edible vegetable products and uses specified in GRN 000061, currently ADM intends to produce plant sterols and plant sterol esters derived from tall oil extracted primarily from pine trees (wood sterols). Although wood sterols manufactured by other companies have already attained GRAS self-affirmed status (GRAS Notices No. GRN 000039 and GRN 000112), this status has not been established for ADM wood sterols. Furthermore, based on current market demands, ADM intends to expand the food use categories indicated in the original GRAS notification to remain competitive with other sterol suppliers and, at the same time, provide an expanded range of sterol-enriched products to the consumer.

Thus, ADM intends to use plant sterols and plant sterol esters, derived from either vegetable oils or tall oil, in the following food categories at a level of up to 0.4 g of free sterol per serving: margarines and vegetable oil spreads, dressings for salads, healthy beverages, health bars, milk type products (including soy milk, ice cream and cream substitutes), cheese and cream, baked foods, adult ready to eat breakfast cereals, mayonnaise, pasta and noodles, sauces, salty snacks, processed soups, puddings, yogurt, adult confections and vegetarian meat analogs; and a level of up to 1 g/serving in fruit/vegetable juices and up to 4% in edible vegetable oils, including diacylglycerol oil as a replacement.

In addition, ADM intends to use Sucrose Fatty Acid Esters (SFAE) as emulsifier in an up to 1:1 ratio with sterols in milk type products (including soy milk, ice cream and cream substitutes) and fruit/vegetable juices at a level of up to 0.4 g per serving.

Product Characteristics and Specifications and Manufacturing Processes

A) Sterols Derived from Edible Vegetable Oils.

Description, chemical composition, specifications and manufacturing process of plant sterols and plant sterol esters derived from edible oils are the same notified to the FDA in the original ADM submission (GRAS Notice No. 000061).

B) Sterols Derived from Tall Oil (Wood Sterols).

1) Product Characteristics and Specifications

The wood sterols product is an off-white powder consisting of a mixture of mainly β-sitosterol, β-sitostanol, campestanol and stigmasterol. Melting range is 135-140°C. They are extracted from tall oil derived primarily from coniferous trees (Pinus pinaster and Pinus syvestris), as part of the wood pulp industry by-product.

The corresponding product specifications are the following:

Total Free Sterols	99% minimum
β-Sitosterol	80% maximum
β-Sitostanol	15% maximum
Campesterol	40% maximum
Campestanol	5% maximum
Stigmasterol	30% maximum
Brassicasterol	6% maximum
Other Sterols	6% maximum
Heavy Metals	10 ppm maximum
Lead	2 ppm maximum

Gas Chromatography (ADM method E-0110)

The following table presents typical sterol compositions of three different production lots (% weight dry bases).

	Lot Number		
	WSP 1004004	WSP 1104005	WSP 1104006
Total free sterols	100%	99.2%	99.0%
β-Sitosterol	78.9%	77.6%	77.8%
β-Sitostanol	10.2%	10.1%	10.0%
Campesterol	7.1%	7.0%	7.1%
Campestanol	1.1%	1.1%	1.0%
Stigmasterol	0.9%	0.9%	0.9%
Brassicasterol	0.0%	0.0%	0.0%
Other sterols	1.8%	2.5%	2.2%

Method of analysis: Gras Chromatography (ADM method E-0110)

All these lots meet the previously indicated specifications and the sterol composition is very consistent from lot to lot.

2) Manufacturing Process of Wood Sterols

The manufacturing flow diagram for the production of wood sterols and wood sterol esters is presented as Appendix A. The starting material is tall oil derived from pine trees (Pinus pinaster and/or Pinus syvestris). As indicated in the diagram, the feedstock, tall oil pitch, is saponified with caustic soda to form soaps from free fatty acids and other saponifiable impurities. Sterols and other unsaponifiable impurities are removed from the soaps by solvent extraction. The soaps are regenerated to free fatty acids by acidulation with sulfuric acid. Sterols are further concentrated by high vacuum, short-path distillation to produce a crude sterol concentrate. This concentrate is then dissolved in solvent, the resulting mixture is cooled to produce pure sterol crystals, and these crystals are isolated by vacuum filtration. The solvent extraction and crystallization steps remove impurities, including terpenoid compounds. The crystals are then dried to remove traces of solvent, and converted to powder or pastilles. Esterification to produce

wood sterol esters is achieved by using standard industry esterification and transesterification methods.

Chemical analyses of the final products indicate that they are free, or at levels below maximum allowed limits for contaminats that include heavy metals, polycyclic aromatic hydrocarbons (PAHs), aflatoxins, residual solvents, pesticide residues, dioxins and terpenoids. Main terpenoid compounds in pine were identified from the literature (5).

Safety and Nutrition Overview

On January 11, 1999, the Lipton Company notified the U.S. FDA of its determination that plant (vegetable oil) sterol esters were Generally Recognized as Safe (FMF 625). This determination was based on an extensive review of the scientific literature and the opinion of an expert panel that evaluated all the existing toxicological and safety information up to 1999. After review of this file, FDA had no objections for the marketing of sterol esters as ingredients in oil spreads (FDA letter from A.M. Rulis to D. Dwyer dated 4/30/99). Lipton's GRAS panel was the same expert panel that has reviewed the present ADM GRAS affirmation for the expansion of food categories. This panel concluded that the extensive human safety information on phytosterol arising from both the free sterol and the sterol ester literature was sufficient to conclude the human safety of phytosterols and for establishing safe exposure limits. Furthermore, the panel concluded that an acceptable daily intake (ADI) was 130 mg/kg/day (as free sterol). For a 70 kg reference man, this level translates to an ADI of 9.1 g/day. It was also established in this report, and later acknowledged by the FDA, that independently of the phytosterol chemical form (free or esterified), the active form, after intestinal hydrolysis was free sterols. Stanol esters have also been recognized as GRAS by the agency (McNeil, FMF 626).

Further safety assessment of plant sterols/stanol and plant sterol/stanol esters, including those derived from tall oil (wood sterols) have been conducted in the U.S. during 2000-2002 by various scientific expert panels. As a result, GRAS status for use in a broad range of food categories has been attained for plant sterol/stanol and plant sterol/stanol esters produced by Novartis Consumer Health (GRN Notice No. 000039), the Procter & Gamble Company (GRN Notice No. 000053), Cargill Inc. (GRAS Notice No. 000048), Archer Daniels Midland Company (GRAS Notice No. GRN 000061), and Teriaka Ltd. (GRAS Notice No. GRN 000112).

In Europe, the safety of plant sterols and plant sterol esters has been reviewed extensively on several occasions during 2002-03 by the Scientific Committee on Foods (SCF, Ref. 6-11), and more recently toward the end of 2003, by a Scientific Panel of the European Food Safety Authority (EFSA, Ref. 12). As a result, the marketing of plant sterols (from vegetable oils and wood sterols) added to a variety of food categories has been authorized by the Directorate General for Health and Consumer Protection (DGSANCO) in the European Community. In addition, the safety of these products has been confirmed recently by a group of independent scientific experts who met in Stresa, Italy, in 2001 to discuss the efficacy and safety of plant stanols and sterols in the management of blood cholesterol levels (Stresa Workshop, Ref. 1, Katan et al. 2003). The main conclusion of all these scientific evaluations has been that sterols are safe for human consumption with only one recommendation: to maintain an adequate

consumption of dietary carotenoid sources (fruit and vegetables) to compensate for an observed, clinically irrelevant, decrease in β-carotene levels. Effects of dietary phytosterols on carotenoids and fat soluble vitamins have been discussed in detail in the original ADM dossier.

The most relevant publications in the last 3 years since the latest safety evaluations of plant sterols by the aforementioned scientific bodies have been: a) A comprehensive review summarizing the deliberations and conclusions of 32 experts on lipids, nutrition and heart disease from various countries who met in Stresa, Italy on March 7-9, 2001, under the auspices of the Nutrition Foundation of Italy, to discuss the efficacy, safety and future of plant sterols and plant sterol esters (Stresa Workshop, Ref. 1. Katan et al. 2003); and b) A long-term clinical study by Hendricks et al. (2003) on the safety of long-term consumption of plant sterols in humans (13).

In the Stresa Workshop, based on a meta-analysis of 41 clinical trials, it was concluded that intake of 2 g/day of plant sterols/stanols reduced low-density lipoprotein cholesterol (LDL-cholesterol) by 10% and that higher sterol intakes added little. This amount can be increased or decreased depending on the composition of the diet and/or the food matrix used for sterol enrichment. Since previous reports showed concerns about the negative effect on the absorption of fat soluble vitamins, a meta-analysis of 10 to 15 trials per vitamin revealed that plasma levels of vitamins A and D are not affected by the consumption of plant sterols/stanols. Alpha carotene, lycopene and vitamin E levels remained stable relative to their carrier molecule, LDL. However, β-carotene levels have consistently declined, within normal levels in most studies, but adverse effects of this phenomenon have not been shown or been expected. It was also indicated that sterol-enriched foods can increase plasma sterols levels, particularly in individuals with phytosterolemia. However, the increased risk of increasing atherosclerosis due to higher levels of blood sterols in patients with homozygous phytosterolemia is believed to be only hypothetical. Regarding a safe upper level of sterol intake, it is also clear that maximum efficacy is around 2-3 g/sterol/day. This is in fact the basis on which EU regulatory bodies such as the SCF and EFSA have recommended in Europe a maximum consumption of 2-3 g/sterol per day. However, as discussed in this review, the 2-3 g/day has been set arbitrarily on efficacy and not on safety. There is no evidence that intakes higher than 2-3 g/day cause any harm, as can be the case with consumers who may be ingesting a wide range of products enriched with sterol/stanols. In closing, the Stresa Workshop participants recognized that the safety testing of sterols and stanols has exceeded that of ordinary food stuffs that are eaten widely and generally considered as safe. Furthermore, adverse effects of the absorption of plant sterols into the circulation appear largely hypothetical, and adverse health outcomes of a decrease in beta-carotene levels in plasma are only speculative and not of major concern.

Hendricks et al. (2003) long-term clinical study (13) is relevant because previous studies in humans had been focused mainly on the efficacy and not on the safety of plant sterols. In addition, all those studies had been of short duration and with a limited number of subjects. The present investigation, using a randomized double-blind placebo-controlled parallel trial, addressed both safety and efficacy of long-term consumption of sterols in 185 subjects consuming daily for a period of one year a 20 g spread enriched with 1.6 g plant sterol esters. Outcome measures included efficacy markers such as total LDL-cholesterol, a large range of safety parameters and reporting of adverse events. Consumption of plant sterols consistently lowered total and LDL-cholesterol during the one year period, on average 4 and 6%, respectively.

However, blood carotenoid concentrations changed over time. Sterol intake reduced lipid adjusted α- and β-carotene concentrations by 15-25% after one year relative to control. Lipid-adjusted fat soluble vitamins remained unchanged. Sterol concentration in serum increased from 2.76 to 5.31 (μmol/mmol total cholesterol) for campesterol and from 1.86 to 2.45 μmol/mmol total cholesterol) for β-sitosterol. The increase in total plant sterol concentration in red blood cells (5.29-9.62 μg/g) did not affect red blood cell deformability. Hormone levels in males (free and total testosterone) and females (luteinizing hormone, follicle stimulating hormone, β-estradiol and progesterone), as well as all clinical chemical and hematological parameters measured were unaffected. Adverse event reporting was not different between subjects consuming the control product vs. the sterol containing product. It is concluded in this investigation that consumption of plant sterol esters-enriched spreads is an effective way to consistently lower blood cholesterol and is safe to use over long periods of time.

Other relevant papers in the literature are either toxicological studies using animal models confirming the safety of sterols and sterol oxidation products (14-15) or short term clinical trials showing the efficacy of plant sterols and its various bioavailabilities when used in different food matrices such as milk, yogurt, bread and cereal (16-17).

One of the animal toxicological studies consists of the safety assessment of sub-chronic oral toxicity of phytosterol esters (14). In this study, rats were fed diets containing phytosterol esters at levels of 0, 0.16, 1.6, 3.2 and 8.1% (w/w) in the diet for 90 days. After a thorough clinical and pathological evaluation, there were no treatment-related changes found that were considered to be of toxicological significance. Therefore, a nominal phytosterol ester concentration of 8.1% was considered to be the no-observed adverse effect level (NOAEL). This was equivalent to 6.6 g/kgBW/day of phytosterol ester, or to 4.1 g/kgBW/day of free sterol.

The other toxicological study addressed the potential genotoxicity and sub-chronic toxicity of phytosterol oxides that may occur in very small amounts under very high temperatures, as a result of phytosterol oxidation (15). The genotoxicity and sub-chronic toxicity of these compounds was assessed in a series of in vitro genotoxicity assays (bacterial mutation, chromosome aberrations and micronucleus) and a sub-chronic feeding study in the rat. It was found that a phytosterol oxide concentrate (approximately 30% phytosterol oxides) did not possess genotoxic potential and no obvious evidence of toxicity was present when oxides were administered to rats for 90 consecutive days. A No-Observed Effect Level (NOEL) for phytosterol oxides was determined to be 128mg/kg/day for males and 144mg/kg/day for females. It was concluded in this investigation that phytosterol oxides show no concerns for human safety.

The data from animal studies suggesting negative effects of high sterol intakes on stroke-prone spontaneously hypertensive (SHRSP) rats (18) and on the modulation of growth of estrogen-responsive breast cancer cells in ovariectomized athymic mice (19) are limited and inconclusive, particularly regarding their significance to human health. Ratnayake et al. (18) reported that plant sterols and plant stanols shorten the lifespan of SHRSP rats and provoke hemorrhagic stroke. These results are, however, equivocal, because the same group of investigators have also indicated that other vegetable oils, in particular olive oil, also shorten the lifespan of SHRSP rats, despite lower amounts of phytosterol in those oils than in canola or corn oil. In addition, SHRSP rats, in contrast to normal rats, absorb excessive amounts of both sterols and stanols and

therefore may not be an appropriate model to reflect what may occur in humans whose intestinal absorption of sterols, and particularly of stanols, is very limited. As discussed in a recent review by Kritchevsky and Chen, these observations in SHRSP rats should not represent a safety concern (20). Regarding modulation of cancer growth, Ju et al. (19) studied the in vitro and in vivo effects of β-sitosterol and β-sitosterol glucoside on the growth of estrogen-responsive breast cancer cells in vitro and in ovariectomized athymic mice. It was found that β-sistosterol can stimulate cancerous growth in vitro. However, in vivo, as part of the diet, β-sitosterol reduced tumor growth. Due to the experimental nature of these latter animal studies, particularly in regard to the type of animal models used, they are considered irrelevant for this safety evaluation.

Taken together, after the latest safety evaluations of plant sterol/stanol esters in 2002-03, the newly generated data has confirmed the safety of plant sterol consumption during long periods of time. However, as confirmed by the latest studies, a consistent observation has been the decrease in plasma carotenoid levels, particularly β-carotene (13, 16, 21). This decrease in plasma carotenoids is considered to have no clinical significance. It is very unlikely to result in a Vitamin A deficiency condition and can be corrected by increasing the consumption of green-leafy vegetables, fruits and other important dietary sources of carotenoids (22).

Estimation of Total Sterol Consumption

The total potential consumption of sterol in all proposed food categories was determined statistically by using the USDA Continuing Survey of Food Intakes by Individuals (CSFII) 1994-96, 98 database (released in 2000) serving sizes established by the Code of Federal Regulations (Part 101.12) and the SAS software (SAS system V9, SAS Institute, Cary, NC). Means and 90th percentiles were determined for individuals (users only) in the population divided in three age groups, as follows: children (3-11 y old), teenagers (12-19 y old) and adults (>20 y old). Infants (<2 y of age) were not included. Calculations were made using a level of addition of sterol of 0.4 g (400 mg) of sterol per serving except for the fruit/vegetable juices category (1 g/serving) and vegetable oil (4% of composition). The consumption of edible oil was estimated consistent with information previously provided by ADM to the FDA on February 24, 2003, as part of the GRAS notification of Enova oil (GRAS notice No. 000115). Since Enova oil, a diacylglycerol oil, is considered to be a replacement for vegetable oil, consequently it is intrinsically included in these calculations.

A summary of the results obtained in this sterol consumption analysis is presented in the following table.

Total Estimated Consumption of Sterols (Mean and 90th Percentile) in Different Age Groups from all Proposed Food Categories

	n*	Mean	**90th Percentile**
Children (3-11 years old)			
Number of Servings/day	6268	4.06	7.11
Grams of sterol/person/day	6268	1.62	2.84
Grams/kgBW/day	5868	0.067	0.123 **(123 mg/kgBW/day)**
Teenagers (12-19 years old)			
Number of Servings/day	1372	5.21	9.83
Grams of sterol/person/day	1372	2.08	3.93
Grams/kgBW/day	1348	0.035	0.067 **(67 mg/kgBW/day)**
Adults (≥ 20 years old)			
Number of Servings/day	9174	5.23	9.72
Grams of sterol/person/day	9174	2.09	3.89
Grams/kgBW/day	9013	0.029	0.055 **(55 mg/kgBW/day)**

* n values differ due to availability of body weight information

Of note in the above table is that the total potential consumption of sterols from all proposed food categories, at the 90th percentile, is below the ADI established in the Lipton petition of 130 mg/kgBW/day in all age groups under consideration. For a 70 kg reference adult individual, the observed sterol intake of 55 mg/kgBW/day at the 90th percentile would be equivalent to 3.9 g sterol/day. However, it should be acknowledged that higher consumption can occur due to directed food product selection.

Estimated Consumption of Sucrose Fatty Acid Esters (SFAE)

The estimation of consumption of SFAE was conducted following the same statistical approach described above, but only on a subset of food items (Categories 5 and 9 in the original ADM dossier that include milk type products and fruit/vegetable juices) whose addition of sterols requires emulsification. The level of SFAE used in the calculations was a 1:1 ratio of sterol:SFAE. That is, each serving of the proposed food item was considered to contain 0.4 g of free sterols and 0.4 g of SFAE. This use level of 0.4 g sterols per serving pertains only to those products requiring the SFAE:Sterol mixture and does not apply to the 1g/serving use level for fruit/vegetable juices not requiring SFAE. A summary of the results of the consumption analysis of SFAE follows.

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Estimation of Sucrose Fatty Acid Ester Intake in Food Categories
(Categories 5 & 9) Requiring Emulsification*

	n**	Mean	**90th Percentile**
Children (3-11 years old)			
Number of Servings/day	2913	0.80	1.56
Grams SFAE/Person/day	2913	0.32	0.62
Grams SFAE/kgBW/day	2715	0.014	0.026
			(26 mg/kgBW/day)
Teenagers (12-19 years old)			
Number of Servings/day	495	1.12	2.08
Grams SFAE/person/day	495	0.45	0.83
Grams SFAE/kgBW/day	485	0.008	0.016
			(16 mg/kgBW/day)
Adults (≥ 20 years old)			
Number of Servings/day	3886	2.41	4.50
Grams SFAE/person/day	3886	0.96	1.80
Grams SFAE/kgBW/day	3818	0.013	0.026
			(26 mg/kgBW/day)

* 1:1 proportion ratio of sterol:SFAE blend (0.4 g of sterol and 0.4 of SFAE)
** n values differ due to availability of body weight information

The ADI established by JECFA (23) and more recently by an EFSA safety review panel (24), has been set at 30 mg/kgBW/day for SFAE. Based on this cut-off point, the 90th percentile consumption values of SFAE for all target age groups are below this 30 mg/kgBW/day limit.

Mitsubishi Chemical Corporation has also estimated that the cumulative exposure of SFAE arising from all uses in the United States, including its use as an approved food additive (21 CFR 172.859), would be 60 mg/person/day (GRAS letter GRN 000129). For a 60 kg reference person this intake of SFAE would be equivalent to 1 mg/kgBW/day. This 1 mg value is supported by available ADM market research on the use of emulsifiers, which indicates an annual use of SFAE in foods in the United States of about 600 metric tons (34). By dividing this volume of SFAE by the projected U.S. population for 2005 by the Census Bureau of 296,000,000 inhabitants, it can be estimated that the intake of this compound is only approximately 6 mg/person/day (0.1 mg/kgBW/day), well below the 60 mg/person/day originally estimated by Mitsubishi Chemical Corporation. For practical purposes, however, if we consider 1 mg/kgBW/day as the estimated cumulative consumption of SFAE from all sources and we add this additional amount to the 26 mg/kgBW/day, the highest 90th percentile value estimated by adding the proposed food categories, the total consumption becomes 27 mg/kgBW/day. This is equivalent to 1.62 g/person/day (27 mg x 60 kg reference person), which is below the NOAEL value of 2 g of SFAE/day, based on clinical studies.

Summary

The safety and health benefits of plant sterols and plant sterol esters have been extensively evaluated by scientists and regulatory agencies in various countries, particularly in the United States and Europe. As a result, market authorizations have been granted to several food

companies for the addition of plant sterols and plant sterol esters, derived from either vegetable oils or from tall oil, to a broad range of food products.

In order to stay competitive in the market, ADM intends to expand the use of plant sterols and its esters, either from vegetable oil or tall oil, to a broader range of food categories than those previously notified to FDA. The plant sterols and plant sterol esters will be added to the following food categories at a level of 0.4 g of free sterol per serving: margarines and vegetable oil spreads, dressings for salads, health beverages, health bars, milk type products (including soy milk, ice cream and cream substitutes), cheese and cream, selected baked foods, adult ready to eat breakfast cereals, mayonnaise, pasta and noodles, sauces, salty snacks, processed soups, puddings, yogurt, adult confections, vegetarian meat analogs and at up to 1 g/serving for fruit/vegetable juices and up to 4% in edible vegetable oils, including diacylglycerol oil as a replacement. Sucrose Fatty Acid Esters (SFAE) up to a level of 1:1 ratio with sterols will be used as emulsifiers in milk type products and fruit/vegetable juices.

The description, chemical composition, specifications and manufacturing process of sterols derived from vegetable oils will be the same notified by ADM to the FDA in the original sterol submission (GRN # 000061). Wood sterols, produced primarily from coniferous trees (P. pinaster and P. syvestris), is an off-white powder composed mainly of β-sitosterol (80% max.), β-sitostanol (15% max.), campesterol (40% max.), campestanol (5% max.) and stigmasterol (30% max.).

The total potential consumption of sterols in all proposed categories was determined statistically (Mean and 90th percentile values) in the U.S. population (users only) using officially recognized databases. Age groups included children (3-11 years old), teenagers (12-19 years old) and adults (>20 years old). 90th percentile values were 123, 67 and 55 mg/kgBW/day for children, teenagers and adults, respectively. All these values are below the ADI level of 130 mg/kgBW/day previously established by Lipton's Scientific Panel as part of Lipton's petition to FDA. For a 60 kg reference person, the observed intake of 55 mg/kgBW/day in an adult individual would be equivalent to 3.3 g of sterol/day.

The consumption of SFAE was determined in a similar statistical approach as described above. 90th percentile values were 26, 16 and 26 mg/kgBW/day for children, teenagers and adults, respectively. These potentially maximum levels are below the ADI value, established by JECFA and later by EFSA, of 30 mg/kgBW/day, even if we consider an additional cumulative consumption of 1 mg/kgBW/day of SFAE from all other sources, including its authorized use as food additive.

Conclusion

We, the expert panel, have independently and collectively critically evaluated the information and data summarized above and conclude that ADM plant sterol and plant sterol esters, derived from either edible vegetable oils or from tall oil (wood sterols), meeting appropriate food-grade specifications and manufactured in compliance with current Good Manufacturing Practice are GRAS by scientific procedures for use at a level of up to 0.4 g/serving in the following food categories and up to 1 g/serving for fruit/vegetable juices and up to 4% in edible vegetable oil, including diacylglycerol oil as a replacement:

1 - Margarine and vegetable oil spreads*
2 - Dressing for salads*
3 - Healthy beverages* (as listed)
4 - Healthy bars*
5 - Milk type products* (includes soy milk, ice cream and cream substitutes)
6 - Cheese and cream*
7 - Selected baked foods*
8 - Adult RTE breakfast cereals
9 - Fruit/vegetable juices
10 - Mayonnaise*
11 - Pasta and noodles
12 - Sauces
13 - Salty snacks
14 - Processed soups
15 - Puddings
16 - Yogurt*
17 - Adult confections
18 - Vegetarian meat analogs
19 - Edible vegetable oil* (includes diacylglycerol oil)

* Categories previously notified by different companies to FDA

Furthermore, SFAE can be used as emulsifier at levels up to 1:1 ratio with sterols in food categories 5 (milk type products) and 9 (fruit/vegetable juices) at a use level of up to 0.4 g/serving.

(b) [redacted]

20 June 2005
Date

Joseph F. Borzelleca, Ph.D.
Professor, Pharmacology and Toxicology
Medical College of Virginia
Richmond, VA

(b) [redacted]

17 June 05
Date

Walter H. Glinsmann, M.D.
President, Glinsmann, Inc.
Arlington, VA

(b) [redacted]

16 June 05
Date

David Kritchevsky, Ph.D.
Caspar Wistar Scholar, Wistar Institute
Philadelphia, PA

(b) [redacted]

22 June 05
Date

Michael Pariza
M.W. Pariza Consulting LLC
Madison, WI

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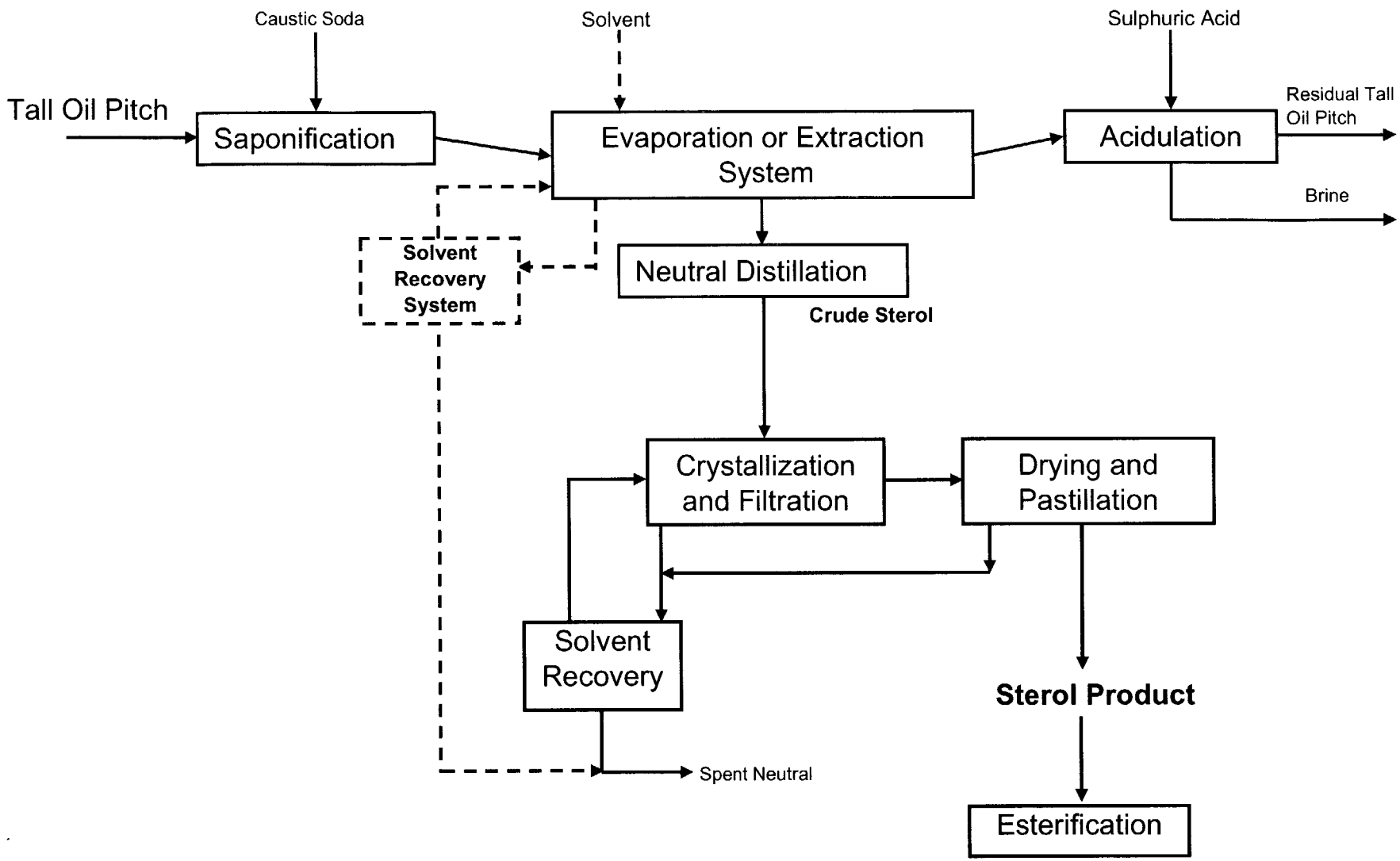
Appendix A

Wood Sterol Process Flow Diagram



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Submission End

AM

James R. Randall Research Center

REC'D SEP 12 2005

September 9, 2005

Dr. Felicia Binion Williams
Division of Biotechnology and GRAS Notice Review, HFS-255
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3836

Re: GRAS Notice No. GRN 000176

Dear Dr. Williams:

As discussed in our recent conversation, we are submitting the following amendments to our Sterol GRAS petition, GRN 000176:

1 - Pages 40-43 should be left blank.

2 - Appendix H and contained sub-appendices 1-8 should be left blank.

3 - The following pages have been modified and are being submitted as part of this amendment (attached):

Pages 000003, 000008, 000010, 000039, 000044.

Please do not hesitate to call me if you have any questions.

Sincerely,

(b)(6)

Mark W. Empie, Ph.D.

MWE/jm

cc: Luis Mejia, Ph.D.

000241

Archer Daniels Midland Company 1001 N. Brush College Rd. Decatur, IL 62521

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VII Appendices 51
A) Sterol GRAS notices issued by FDA to several companies
B) Structure formulas of main wood sterol components
C) Manufacturing flow diagram of wood sterols
D) Analyses of pesticide residues in wood sterols
E) Dioxin analysis of wood sterols
F) EFSA evaluation of plant sterols
G) Estimation of phytosterol intake by the U.S. population from the consumption of ADM's proposed food categories
H) (This section is left blank)
I) ADM expert GRAS panel report of phytosterol applied to an expanded range of food categories

[redacted]

notified to FDA on October 27, 2000 (GRAS Notice No. GRN 000061, April 18, 2001) and an expanded range of food categories, i.e., margarines and vegetable oil spreads, dressings for salads, healthy beverages, health bars, milk type products (including soy milk, ice cream and cream substitutes), cheese and cream, baked foods, adult ready to eat breakfast cereals, fruit/vegetable juices, mayonnaise, pasta and noodles, sauces, salty snacks, processed soups, puddings, yogurt, adult confections, vegetarian meat analogs and edible vegetable oils, including diacylglycerol oil as a replacement.

In terms of the plant sterols and sterol esters from vegetable oils, neither the product specifications nor the manufacturing process have changed from the original notification, as described in the GRN 000061. For those plant sterols and sterol esters from tall oils (i.e., "wood sterols"), the manufacturing information is provided below as part of this notification.

Safe and suitable emulsifiers will be used for food applications requiring emulsification, such as lecithins, sucrose fatty acid esters, mono and diglycerides of fatty acids, polysorbates and polyglycerol esters of fatty acids.

[redacted]

As noted by the asterisks, the above list includes the food categories already authorized by the Agency to Lipton/Unilever (FDA letter from A.M. Rulis to D. Dwyer on 4/30/99), ADM (GRAS Notice No. 000061), Teriaka Ltd. (GRAS Notice No. 000112), Cargill (GRAS Notice No. 000048), Novartis Consumer Health (GRAS Notice No. 000039) and Procter & Gamble (GRAS Notice No. GRN 000053). The specific foods are identified in the attached appendices according to food codes listed in the U.S. Department of Agriculture (USDA) 1994-1996, 98 Continuing Survey of Food Intake by Individuals (CFSII 94-96-98), and these codes have been used to calculate the estimated daily intake (EDI) values for the consumption of plant sterols and plant sterol esters in the already indicated age groups of the U.S. population.

E) Basis for GRAS Determination

1) Description of Safety Data

Pursuant to 21 CFR 170.30, ADM has determined that plant sterol and plant sterol esters, derived from either vegetable oils or tall oil, are GRAS substances for the intended applications based upon scientific procedures and by the supportive opinion of an external panel of experts (Appendix I). The four-member panel consisted of the same scientists in Lipton's GRAS panel which

However, it should be acknowledged that higher consumption can occur due to directed food product selection.

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V Conclusion

Based on the information presented here, it can be concluded that plant sterols and sterol esters, derived from either vegetable oils or from tall oil (wood sterols), are GRAS for the intended use in an expanded range of food categories. These sterols may also be incorporated into certain food applications through the use of safe and suitable emulsifiers. ADM bases its GRAS conclusion on a critical review of the sterol literature, all technical information presented here, and the estimated consumption levels of sterols which are below established ADI values of 130 mg/kgBW/.

Reference List for Industry Submission, GRN 000176

EFSA (2003). Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to a novel food application from Forbes Medi-Tech for approval of plant sterol-containing milk-based beverages. European Food Safety Authority, 25 November 2003.

Food and Drug Administration, HHS, Code of Federal Regulation, 21 CFR 172.859, Sucrose Fatty Acid Esters.

Food Chemicals Codex, Fourth Edition, First Supplement (1 997).

JECFA (1 998). Safety evaluation of certain food additives and contaminants. Sucrose ester of fatty acids and sucroglycerides. WHO Food Additive Series 40, World Health Organization, Geneva (INS 473, 1997).

EFSA (2004). Opinion of the Scientific Panel on Food Additives, flavourings, processing aids and materials in contact with foods on sucrose esters of fatty acids, E473 and sucroglycerides, E474 based on a request from the Commission related to sucrose esters of fatty acids (E473). The EFSA Journal 106: 1-24.