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ORIGINAL SUBMISSION

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**THE GENERALLY RECOGNIZED AS SAFE (GRAS)
STATUS OF SUCROSE MONOESTERS OF LAURIC
ACID, PALMITIC ACID AND STEARIC ACID AS
EMULSIFYING AGENTS FOR FLAVORS USED IN
FRUIT FLAVORED BEVERAGES**

Prepared for:

Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied
Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD
U.S.A. 20740-3835

Prepared by:

Compass Foods Pte Ltd
6 Tuas Basin Close
Singapore
638799

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APR 08 2008

BY:.....



March 17th, 2008

Robert L. Martin
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD
U.S.A. 20740-3835

Re: GRAS Notification

Dear Dr. Martin:

In accordance with proposed 21 CFR §170.36 [Notice of a claim for exemption based on a Generally Recognized As Safe (GRAS) determination] published in the Federal Register (62 FR 18939-18964), I am submitting in triplicate, as the notifier, Compass Foods Pte Ltd, 6 Tuas Basin Close, Singapore, 638799, a Notice of the determination, on the basis of scientific procedures, that sucrose monoesters of lauric acid, palmitic acid and stearic acid is GRAS for use as emulsifiers in flavor concentrates for use in fruit flavored beverages and therefore, is exempt from the premarket approval requirements of the *Federal, Food, Drug and Cosmetic Act*. Information setting forth the basis for the GRAS determination, which includes a comprehensive summary of the data available and reviewed by an independent panel of experts (the Expert Panel) in support of the safety of sucrose monoesters of lauric acid, palmitic acid and stearic acid under the intended conditions of use, as well as *curricula vitae* evidencing the qualifications of the members of the Expert Panel for evaluating the safety of food ingredients, also is enclosed for review by the agency.

Should you have any questions or concerns regarding this GRAS Notice, please do not hesitate to contact me at any point during the review process so that we may provide a response in a timely manner. I look forward to receiving acknowledgement of receipt of this notice.

Sincerely,

Bob Comstock
Managing Director

Enclosures

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BY:.....

April 7th, 2008

APR 08 2008

Robert L. Martin
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD
U.S.A. 20740-3835

Re: GRAS Notification

Dear Dr. Martin:

In accordance with proposed 21 CFR §170.36 [Notice of a claim for exemption based on a Generally Recognized As Safe (GRAS) determination] published in the Federal Register (62 FR 18939-18964), please find enclosed two additional copies of a Notice of the determination, on the basis of scientific procedures, that sucrose monoesters of lauric acid, palmitic acid and stearic acid is GRAS for use as emulsifiers in flavor concentrates for use in fruit flavored beverages. As discussed, an original copy of this notification was submitted by Compass Foods Pte Ltd, 6 Tuas Basin Close, Singapore, 638799, on April 1st, 2008 and these binders will complete the submission in triplicate.

Should you have any questions or concerns regarding this GRAS Notice, please do not hesitate to contact me at any point during the review process so that we may provide a response in a timely manner. I look forward to receiving acknowledgement of receipt of this notice.

Sincerely,

Bob Comstock
Managing Director

Enclosures

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I GRAS Exemption Claim

BY:

A. Claim of Exemption From the Requirement for Premarket Approval Pursuant to Proposed 21 CFR §170.36(c)(1) [62 FR 18938 (17 April 1997)]

Sucrose monoesters of lauric acid, palmitic acid and stearic acid have been determined to be Generally Recognized As Safe (GRAS) by Compass Foods Pte Ltd. consistent with Section 201(s) of the *Federal Food, Drug, and Cosmetic Act*. This determination is based on scientific procedures as described in the following sections, under the conditions of its intended use in food, among experts qualified by scientific training and expertise. Therefore, the use of sucrose monoesters of lauric acid, palmitic acid and stearic acid used in flavor concentrates that are eventually used in fruit-flavored beverages as described below is exempt from the requirement of premarket approval.

Signed,

24-MARCH-08

Date

Bob Comstock
12 Tuas Avenue 1
Singapore
639497

B. Name and Address of Notifier

Mr. Bob Comstock
Managing Director
Compass Foods Pte Ltd
12 Tuas Avenue 1
Singapore
639497

Tel: 011-65-6863-1971
Email: bob@compassfoods.com

C. Common Name of the Notified Substance

Sucrose monoesters of fatty acids

D. Conditions of Intended Use in Food

Sucrose fatty acid esters are currently approved for use in a variety of food categories including baked goods and baking mixes, chewing gum, coffee and tea with added dairy ingredients or

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dairy product analogues, confections and frostings, dairy product analogues, frozen dairy desserts and whipped milk products, and surimi-based fabricated seafood products. In addition, they are used as protective coatings applied to fresh apples, avocados, bananas, plantains, limes, melons (honeydew and cantaloupe), papaya, peaches, pears, pineapples and plums to retard ripening and spoiling. Currently the intended proposed use for sucrose monoesters of lauric acid, palmitic acid and stearic acid is as emulsifiers for preparation of fruit flavor concentrates used in preparation of fruit flavored beverages at levels up to 50 ppm in beverages as consumed. The individual existing food-uses and proposed food-uses and use-levels for sucrose fatty acid esters employed in the current intake analysis are summarized in Table D-1. Food codes representative of each proposed food-use were chosen from the NHANES 2003-2004 (CDC, 2006; USDA, 2006). Food codes were grouped in food-use categories according to Title 21, Section §170.3 of the Code of Federal Regulations (CFR, 2006a). Product-specific adjustment factors were developed based on data provided in the standard recipe file for the CSFII 1994-1996, 1998 survey (USDA, 2000).

Food Category	Proposed Food-Uses	Sucrose Esters of Fatty Acid Use Levels	Flour Content	Use-Levels (%)
Baked Goods and Baking Mixes	Biscuit mixes	-	-	1.0
	Cakes	-	-	0.5
	White breads	1.0% by weight of flour	1 – 55%	0.01 to 0.55
	White rolls	1.0% by weight of flour	1 – 48%	0.01 to 0.48
Chewing Gum	Chewing gum	-	-	0.5
Confections and Frostings	Frostings	-	-	0.5
Dairy Product Analogs	Coffee whiteners	-	-	0.5 to 1.0
Fats and Oils	Margarine	-	-	0.5
Fish Products	Surimi based fish products	-	-	1.0
Fresh Fruits and Vegetables	Raw fruits	-	-	0.0056 – 0.0083
Frozen Dairy Desserts	Ice cream, ice milk and sherbet	-	-	0.3
Milk Products	Dairy-based toppings	-	-	2.0
Processed Fruits and Fruit Juices	Fruit-flavored beverages	-	-	0.005

The consumption of all foods for which sucrose esters are proposed for use as well as those in which sucrose esters are currently permitted for use resulted in estimated mean all-person and all-user intakes of sucrose fatty acid esters of 334.8 mg/person/day (5.7 mg/kg body weight/day/day) and 336.9 mg/person/day (5.7 mg/kg body weight/day/day), respectively. The 90th percentile all-person and all-user intakes of sucrose fatty acid esters from all existing and proposed food-uses by the total population were 697.5 mg/person/day (12.6 mg/kg body weight/day) and 698.7 mg/person/day (12.6 mg/kg body weight/day), respectively.

When the intake of sucrose fatty acid ester from fruit beverages alone was considered, the estimated all-person and all-user intakes in the total population were determined to be 20.8 mg (0.30 mg/kg body weight/day) and 29.5 mg (0.43 mg/kg body weight/day). The estimated 90th percentile all-person and all-user intakes of sucrose fatty acid esters were 53.8 mg (0.75 mg/kg body weight/day) and 63.7 mg (0.90 mg/kg body weight/day). The estimated exposure from the new proposed use represents a small percentage of the current intakes.

E. Basis for the GRAS Determination

Pursuant to 21 CFR § 170.30, sucrose monoesters of lauric acid, palmitic acid and stearic acid has been determined to be GRAS on the basis of scientific procedures. This determination is based on the views of experts who are qualified by scientific training and experience to evaluate the safety of sucrose monoesters of lauric acid, palmitic acid and stearic acid as a component of beverages. The safety of sucrose monoesters of lauric acid, palmitic acid and stearic acid is supported by a number of published studies on sucrose monoesters of lauric acid, palmitic acid and stearic acid, including metabolic studies, acute, subchronic and chronic toxicity studies in experimental animals and human studies investigating the effects of sucrose monoesters of lauric acid, palmitic acid and stearic acid. This determination is further supported by an expert panel evaluation of the health aspects of sucrose monoesters of lauric acid, palmitic acid and stearic acid. (See Attached – EXPERT PANEL REPORT CONCERNING THE GENERALLY RECOGNIZED AS SAFE STATUS OF SUCROSE MONOESTERS OF LAURIC ACID, PALMITIC ACID AND STEARIC ACID AS EMULSIFYING AGENTS FOR FLAVORS USED IN FRUIT FLAVORED BEVERAGES).

F. Availability of Information

The data and information that serve as the basis for this GRAS Notification will be sent to the U.S. Food and Drug Administration (FDA) upon request, or will be available for review and copying at reasonable times at the offices of:

Mr. Bob Comstock
Managing Director
Compass Foods Pte Ltd
12 Tuas Avenue 1
Singapore

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639497

Tel: 011-65-6863-1971

Email: bob@compassfoods.com

Should the U.S. Food and Drug Administration (FDA) have any questions or additional information requests regarding this notification, Compass Foods Pte Ltd. will supply these data and information.

II. Detailed Information About the Identity of the Substance

A. Identity

All three materials, sucrose monolaurate, sucrose monopalmitate and sucrose monostearate are white to grayish powders. Generally, these materials have higher HLB (hydrophobic-hydrophilic balance) values (better emulsifying properties) in the range of 18 than other sucrose fatty acid esters because of their higher monoester content which is greater than 90%. They are generally soluble in water but insoluble in ethanol. They have variable melting temperatures, sucrose monolaurate in the range of 35 to 47°C, sucrose monopalmitate in the range of 40 to 48°C and sucrose stearate in the range of 40 to 56°C. They all decompose at high temperatures, >235°C.

Common or Usual Name:

Sucrose esters of fatty acids
Sucrose fatty acid esters
Sucroglycerides
Sucrose monoester of lauric acid
Sucrose monoester of palmitic acid
Sucrose monoester of stearic acid
Sucrose monolaurate
Sucrose monopalmitate
Sucrose monostearate

Chemical Name:

Sucrose monolaurate
Alpha-D-glucopyranoside, beta-D-fructofuranosyl, monododecanoate
Beta-D-fructofuranosyl-alpha-D-glucopyranoside, monododecanoate

Sucrose monopalmitate
Alpha-D-glucopyranoside, beta-D-fructofuranosyl, monohexadecanoate
Beta-D-fructofuranosyl-alpha-D-glucopyranoside, monohexadecanoate

Sucrose monostearate
Alpha-D-glucopyranoside, beta-D-fructofuranosyl, monoctadecanoate

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Beta-D-fructofuranosyl-alpha-D-glucopyranoside,monoctadecanoate

Chemical Abstracts Service (CAS) Number:

Sucrose monolaurate	25339-99-5
Sucrose monopalmitate	26446-38-8
Sucrose monostearate	25168-73-4

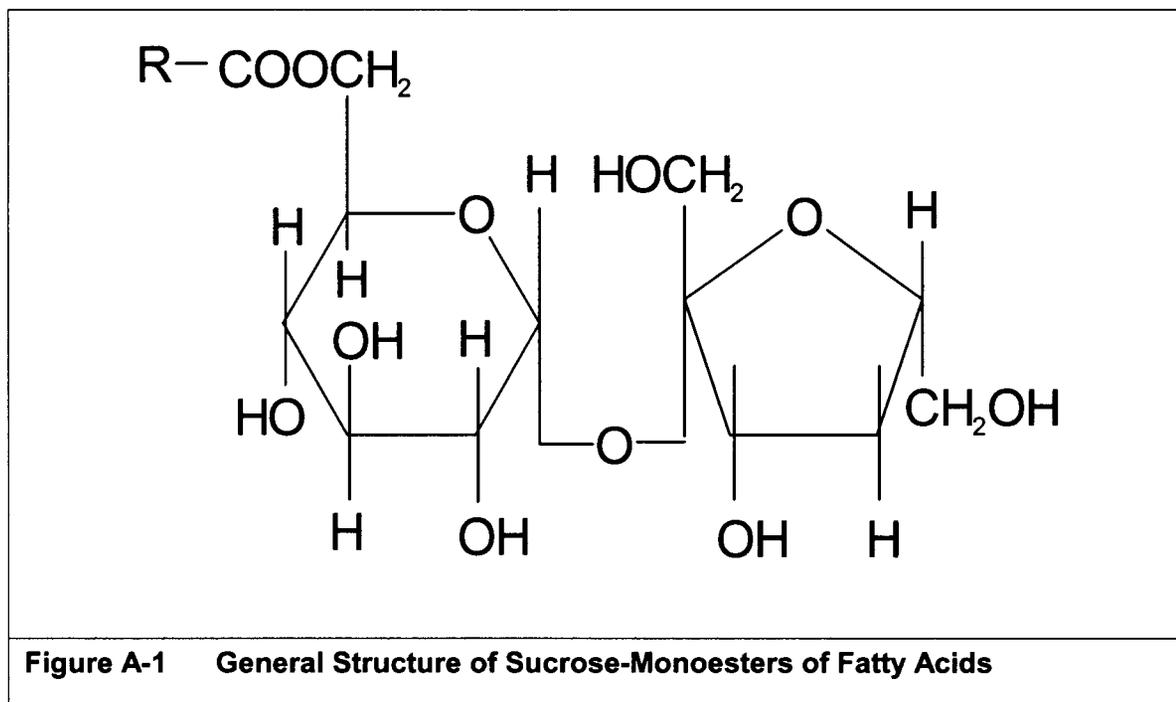
Empirical Formula and Formula Weight:

Sucrose monolaurate	$C_{24}H_{44}O_{12}$
Sucrose monopalmitate	$C_{28}H_{52}O_{12}$
Sucrose monostearate	$C_{30}H_{56}O_{12}$

Molecular weight:

Sucrose monolaurate	524.6
Sucrose monopalmitate	580.7
Sucrose monostearate	608.8

Structural Formula:



B. Method of Manufacture

The method of manufacture is different from the traditional method of manufacture for sucrose esters of fatty acids in that the starting fatty acid esters are vinyl esters rather than the traditional methyl esters of fatty acids. This change in manufacturing method results in trace levels of other residual chemicals not found in traditional sucrose esters of fatty acids

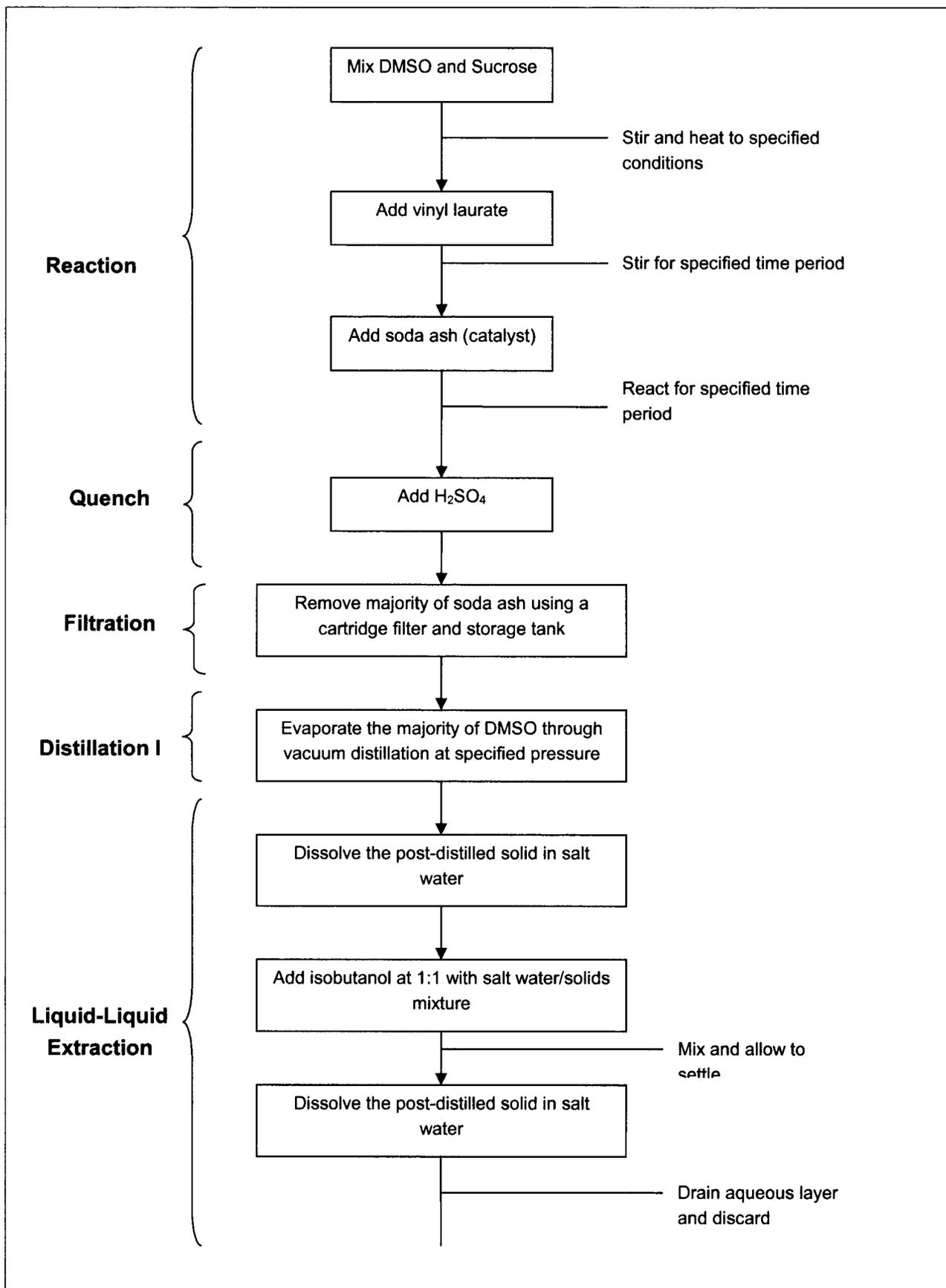
The reaction sequence involves the initial reaction of sucrose with the vinyl fatty acid esters followed by a series of purification steps to remove reaction solvents and the fatty acid vinyl ester starting materials.

Sucrose is mixed with dimethylsulfoxide (DMSO) for 30 minutes with heating of the mixture to 60°C. The vinyl ester of fatty acid (*e.g.*, vinyl laurate) is added to the reaction mixture and stirred for an additional 30 minutes. The reaction is started by the addition of soda ash to the mixture for a period of 5 minutes until the addition of sulphuric acid to neutralize the reaction.

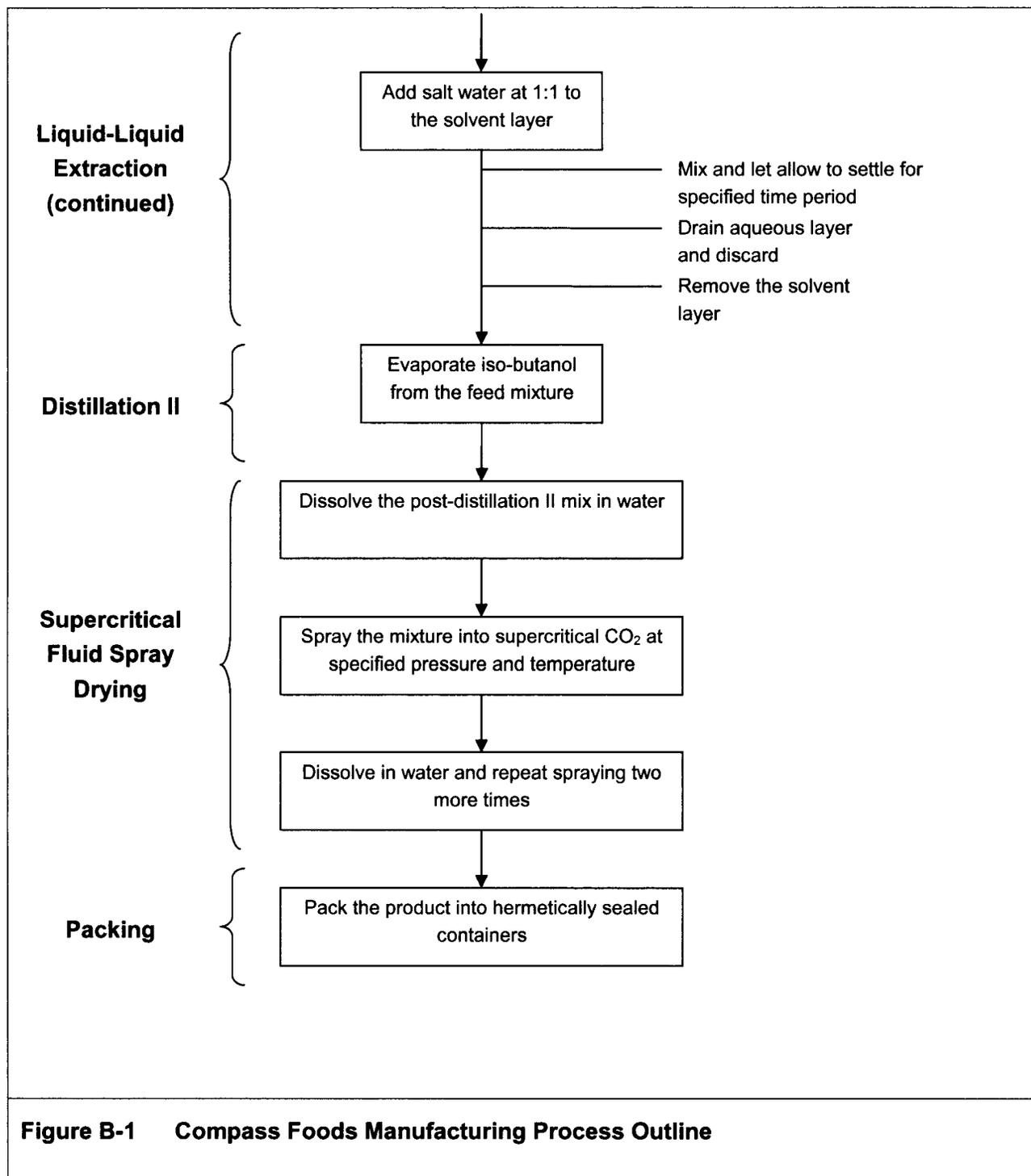
The insoluble soda ash is removed by filtration and the DMSO removed by distillation which is repeated twice. The solid is dissolved in salt water and extracted with isobutanol (1:1 v/v of water). The aqueous layer is discarded and the solvent layer extracted with an equal volume of salt solution and the aqueous layer is discarded. The solvent is removed by distillation and the residue mixed with water. The mixture is sprayed into supercritical CO₂ to remove solvent residues. The treatment with supercritical CO₂ is repeated twice more. The remaining solid material is packaged into hermetically sealed containers.

A detailed outline of the manufacturing method is presented in Figure 2.

SUCROSE MONOESTERS OF LAURIC ACID, PALMITIC ACID AND STEARIC ACID NOTIFICATION



SUCROSE MONOESTERS OF LAURIC ACID, PALMITIC ACID AND STEARIC ACID NOTIFICATION



C. Specifications for Food Grade Material

In order to ensure consistent product, Compass Foods Pte Ltd. has established specifications for the final ingredients for sucrose monoesters of lauric acid, palmitic acid and stearic acid (see Table 1). These specifications are almost identical to the current specifications listed for sucrose esters of

SUCROSE MONOESTERS OF LAURIC ACID, PALMITIC ACID AND STEARIC ACID NOTIFICATION

fatty acids. Representative lots are routinely assayed to ensure compliance with final product chemical and physical specifications. The manufactured lots also meet the specifications for sucrose esters of fatty acids.

Specification Parameter	Specification Limit	Method
Identification		
A. Presence of fatty acid	Positive	FCC (2003)
B. Presence of carbohydrate	Positive	FCC (2003)
Purity		
Assay	Not less than 92% combined mono, and diesters	FCC (2003)
Monoester content	Not less than 83%	Internal validated HPLC method
Acid value	Not more than 6	FCC (2003)
Free sucrose	Not more than 5%	FCC (2003)
Residue on Ignition	Not more than 2%	FCC (2003)
Lead	Not more than 2 mg/kg	FCC (2003)
Dimethylsulfoxide	Not more than 2 mg/kg	FCC (2003)
Isobutanol	Not more than 10 mg/kg	FCC (2003)

C.1 Levels of New Residual Chemicals

Due to residual levels present in the final sucrose monoesters, the potential exists for an intake of impurities such as vinyl fatty acid esters, acetaldehyde and MEHQ (p-methoxyphenol, p-hydroxyanisole). The residual levels of these impurities are summarized in Table C.1-1, with the potential intake resulting from these levels summarized in Table C.1-2.

Products	Vinyl Ester Content (ppm)	Acetylaldehyde Content (ppm)	MEHQ Content (ppb)
Sucrose Laurate	<25	26.23 – 30.04	-
Sucrose Palmitate	<10	17.36 – 28.26	<100
Sucrose Stearate	48.09 – 111.23	20.09 – 48.29	<100

To calculate the values presented in Table 5.4-2, the mean and 90th percentile all-user intakes of sucrose fatty acid esters from fruit flavored beverages by the total population were multiplied by the highest reported content of the chemical impurities in sucrose laurate, sucrose palmitate, or sucrose stearate.

SUCROSE MONOESTERS OF LAURIC ACID, PALMITIC ACID AND STEARIC ACID NOTIFICATION

Population Group	Vinyl Ester All-User Intake (µg/person/day)		Acetylaldehyde All-User Intake (µg/person/day)		MEHQ All-User Intake (ng/person/day)	
	Mean	90 th Percentile	Mean	90 th Percentile	Mean	90 th Percentile
Total Population	3.28	7.08	1.43	3.08	2.95	6.37

The exposure to vinyl esters, p-methoxyphenol, and acetaldehyde in these product types was determined to be trivial as compared to existing safety data (see attached EXPERT PANEL REPORT).

III. Self-Limiting Levels of Use

Use of sucrose monoesters for solubilization of beverage flavors is self limiting since use of sucrose monoesters beyond the optimal ratio of 0.5 to 1 with the flavor by weight will result in the lack of clarity in the beverage and excessive foaming, both undesired beverage characteristics.

IV. Basis for GRAS Determination

The determination that sucrose monoesters of lauric acid, palmitic acid and stearic acid are GRAS is on the basis of scientific procedures. (See Attached –EXPERT PANEL REPORT CONCERNING THE GENERALLY RECOGNIZED AS SAFE STATUS OF SUCROSE MONOESTERS OF LAURIC ACID, PALMITIC ACID AND STEARIC ACID AS EMULSIFYING AGENTS FOR FLAVORS USED IN FRUIT FLAVORED BEVERAGES).

**EXPERT PANEL CONSENSUS STATEMENT REGARDING THE
GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF SUCROSE
MONOESTERS OF LAURIC ACID, PALMITIC ACID AND STEARIC ACID
AS EMULSIFYING AGENTS FOR FLAVORS USED IN FRUIT
FLAVORED BEVERAGES**

September 28th, 2007

INTRODUCTION

Compass Foods Pte Ltd. wishes to market sucrose monoesters of lauric acid, palmitic acid and stearic acid as emulsifiers in flavor concentrates for use in fruit flavored beverages. Compass Foods Pte Ltd assembled an Expert Panel (the "Panel") of independent scientists, qualified by their relevant national and international experience and scientific training to evaluate the safety of food ingredients, to conduct a critical and comprehensive evaluation of the available pertinent data and information, and to determine the safety and the Generally Recognized As Safe (GRAS) status based on scientific procedures of the intended use of the sucrose monoesters identified above. The Expert Panel convened on 28 September 2007. The Panel consisted of the below-signed qualified scientific experts: Dr. Joseph F. Borzelleca (Medical College of Virginia), Dr. Robert J. Nicolosi (University of Massachusetts, Lowell), and Dr. John A. Thomas (Indiana University). *Curricula vitae* evidencing the Panel members' qualifications for evaluating the safety of food ingredients are provided in Attachment 1.

Sucrose fatty acid esters are currently regulated by the U.S. Food and Drug Administration (FDA) as food additives under chapter 21, section 172.859 of the Federal Code of Regulations (CFR) pertaining to their use as emulsifiers, texturizers and protective coatings for fresh fruit and are considered safe for inclusion in food provided they are used at levels at or below that outlined in the regulation (FDA, 2007). Sucrose fatty acid esters are permitted as emulsifiers in baked goods and baking mixes, in chewing gum, in coffee and tea beverages with added dairy ingredients and/or dairy product analogs, in confections and frostings, in dairy product analogs, in frozen dairy desserts and in whipped milk products. They are also permitted as texturizers in biscuit mixes, in chewing gum, in confections and frosting and in surimi-based fabricated seafood products. In addition they are permitted for use as components of protective coatings applied to fresh apples, avocados, bananas, plantains, limes, melons (honeydew and cantaloupe), papaya, peaches, pears, pineapples and plums to retard ripening and spoiling.

The following issues relevant to the safety assessment for the use of sucrose monoesters of lauric acid, palmitic acid and stearic acid as emulsifiers in flavor concentrates for use in fruit flavored beverages will be discussed in this dossier: the manufacture and intended uses of

sucrose monoesters of lauric acid, palmitic acid and stearic as emulsifiers in flavor concentrates added to fruit flavored beverages; the consumption of sucrose fatty acid esters through their current allowed uses and proposed new uses; the literature regarding the toxicology of sucrose fatty acid esters; and the safety assessment of sucrose monoesters of lauric acid, palmitic acid and stearic acid under their conditions of intended use.

The Panel, independently and collectively, critically examined a comprehensive package of scientific information and data compiled from the literature and other published sources through June 2007. In addition, the Panel evaluated other information deemed appropriate or necessary, including data and information provided by Compass Foods Pte Ltd. The data evaluated by the Panel included information pertaining to the method of manufacture and product specifications, supporting analytical data, intended use-levels in specified food products, consumption estimates for all intended uses, and a comprehensive assessment of the available scientific literature pertaining to the safety of sucrose fatty acid esters and impurities.

Following independent, critical evaluation of such data and information, the Panel unanimously concluded that the proposed use of sucrose monoesters of lauric acid, palmitic acid and stearic acid meeting food grade specifications and manufactured in accordance with current Good Manufacturing Practice (cGMP), as emulsifiers for flavors added to fruit flavored beverages is safe and Generally Recognized As Safe (GRAS) based on scientific procedures. A summary of the basis for the Panel's conclusion is provided below.

MANUFACTURING AND COMPOSITION

The reaction sequence involves the initial reaction of sucrose with the fatty acid vinyl esters followed by a series of purification steps to remove reaction solvents and the fatty acid vinyl ester starting materials.

Sucrose is mixed with DMSO with heating and the vinyl ester of fatty acid (*e.g.*, vinyl laurate) is added to the reaction mixture with stirring. Following temperature equilibration, the reaction is started by the addition of soda ash to the mixture for a short time period until the addition of sulphuric acid to neutralize the reaction.

The insoluble soda ash is removed by filtration and the DMSO is removed by distillation which is repeated twice. The solid is dissolved in salt water and extracted with isobutanol (1:1 v/v of water). The aqueous layer is discarded and the solvent layer extracted with an equal volume of salt solution and the aqueous layer is discarded. The solvent is removed by distillation and the residue mixed with water. The mixture is sprayed into supercritical CO₂ to remove solvent residues. The treatment with supercritical CO₂ is repeated twice more. The remaining solid material is packaged into hermetically sealed containers.

All of the materials employed in the manufacturing of the sucrose monoesters are of a food grade quality or of high purity and are employed in a manner consistent with current Good Manufacturing Practice (cGMP). The product specifications for the sucrose esters are provided as Attachment 2. The manufacturing process results in small levels of vinyl fatty acid residues, acetaldehyde (formed from vinyl portion of vinyl fatty acid esters), and p-methoxyphenol (stabilizer in vinyl fatty acid ester starting material), the safety of which is addressed below.

Considering that these sucrose fatty acid esters are stored at room temperature as dry powders, they are expected to be stable for at least 2 years. A study of the stability of the finished product currently being conducted by Compass, and the interim results of the study demonstrate that there is no significant decrease in the sucrose palmitate monoester content of the product over a period of 8 months.

Sucrose monoesters are sensitive to pH and temperature conditions undergoing hydrolysis to sucrose and free fatty acids. Maximum stability occurs around pH 4 to 5 which is the pH range in fruit flavored beverages. At temperatures of 25°C, very little hydrolysis would occur over the course of several weeks.

INTENDED USE AND ESTIMATED EXPOSURE

Sucrose esters of fatty acids manufactured using the fatty acids derived from edible tallow, hydrogenated edible tallow or edible vegetable oils are approved food additives under 21 C.F.R. §172.859 for use as emulsifiers. Sucrose fatty acid esters have also been GRASed for additional uses including use as an emulsifier in beta carotene color preparations used in beverages, crackers, soups and sauces (GRAS Notification GRN 000129). The estimated intake from this specific use was estimated to be 8 mg/day at the 90th percentile intake. This trivial amount was not included in the total intake estimates discussed in the following paragraphs. The existing and proposed food uses for sucrose fatty acid esters included in the current intake assessment include the following food categories: baked goods and baking mixes (biscuit mixes, cakes, white breads, and white rolls), chewing gum, confections and frostings (frostings), dairy product analogs (coffee whiteners), fats and oils (margarine), fish products (surimi based fish products), fresh fruits and vegetables (fresh fruits), frozen dairy desserts (ice cream, ice milk and sherbet), milk products (dairy-based toppings), and processed fruits and fruit juices (fruit-flavored beverages). Proposed levels of use in fruit flavored beverages are relatively low (50 ppm).

Consumption of foods in the 2003-2004 NHANES survey for which sucrose esters are currently approved for use by the total U.S. population resulted in estimated mean all-person and all-user intakes of sucrose fatty acid esters of 319.2 mg/person/day (5.4 mg/kg body weight/day) and 326.8 mg/person/day (5.5 mg/kg body weight/day), respectively. The 90th percentile all-person and all-user intakes of sucrose fatty acid esters from all existing food-uses by the total

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population were 680.9 mg/person/day (12.1 mg/kg body weight/day) and 688.3 mg/person/day (12.2 mg/kg body weight/day), respectively. The consumption of all foods for which sucrose esters are proposed for use as well as those in which sucrose esters are currently permitted for use resulted in estimated mean all-person and all-user intakes of sucrose fatty acid esters of 334.8 mg/person/day (5.7 mg/kg body weight/day) and 336.9 mg/person/day (5.7 mg/kg body weight/day), respectively. The 90th percentile all-person and all-user intakes of sucrose fatty acid esters from all existing and proposed food-uses by the total population were 697.5 mg/person/day (12.6 mg/kg body weight/day) and 698.7 mg/person/day (12.6 mg/kg body weight/day), respectively.

Estimated all-person and all-user intakes from proposed uses in fruit flavored beverages in the total population were determined to be 20.8 mg (0.30 mg/kg bw) and 29.5 mg (0.43 mg/kg bw). The estimated 90th percentile all-person and all-user intakes of sucrose fatty acid esters were 53.8 mg (0.75 mg/kg bw) and 63.7 mg (0.90 mg/kg bw). The estimated exposure from the new proposed use is only a small percentage of the current intakes.

The type of intake methodology used to estimate intakes of sucrose esters is generally considered to be 'worst case' as a result of several conservative assumptions made in the consumption estimates. For example, it is often assumed that all food products within a food category contain the ingredient at the maximum specified level of use. In addition, it is well established that the length of a dietary survey affects the estimated consumption of individual users. Short-term surveys, such as the typical 2- or 3-day dietary surveys, overestimate consumption of food products that are consumed relatively infrequently.

DATA PERTAINING TO THE SAFETY OF SUCROSE ESTERS

A number of published toxicity studies exist for sucrose fatty acid esters that consist of a mixture of stearic acid and palmitic acid (70/30) where some of the preparations are primarily monoesters with lesser amounts of diesters and triesters. Other preparations consist of mixtures of lower levels of monoesters but higher amounts of diesters and triesters. The monoesters are completely hydrolyzed by the intestinal cells prior to absorption but the higher esters are not hydrolyzed completely and thus are not absorbed and are excreted in the feces. These toxicological studies are supported by several tolerance and safety studies in humans. Since no safety issues were noted in high dose chronic animal studies, the ADI for these compounds has been determined from human studies that show physiological effects (soft stools) at doses of 2 grams and greater per day.

No toxicology studies including ADME were identified for sucrose monolaurate. Since the monoesters are almost completely hydrolyzed by the intestinal cells prior to absorption, their safety can be assessed on the basis of sucrose and the fatty acid, for example, lauric acid.

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General Fat Digestion and Absorption

The stomach is the major site of fat emulsification, by way of mechanical fragmentation of larger lipid masses. Triglycerides (TGs), are hydrolyzed by a lingual lipase secreted by the dorsal surface of the tongue and a gastric lipase secreted by the stomach. Gastric lipase initiates lipid digestion by hydrolyzing short-, medium-, and generally unsaturated long-chain fatty acids that are present in the *sn*-3 position from the TG. The free short- and medium-chain fatty acids (containing ≤ 12 carbon atoms) are hydrophilic and can be absorbed *via* the stomach wall into the portal vein, while longer chain fatty acids (containing >12 carbon atoms) and the remaining diglycerides (DG) and TG are transported into the duodenum in fat droplets, and hydrolyzed in a reaction catalyzed by pancreatic lipase. Lipid droplets smaller than $0.5 \mu\text{m}$ are pushed into the duodenum, where the emulsion droplets are exposed to bile. The concentration of bile acids is usually well above a critical level where micelles (water soluble aggregates) are formed upon mixing with digested lipids. Micelles are 100 to 500 times smaller in diameter than emulsion particles, which make for a water-clear micellar solution in the proximal small intestine (Wahbeh and Christie, 2006).

The size of the emulsion particles resulting from formulations containing sucrose monolaurate, monopalmitate or monostearate are generally in the range of 20 nm that are considered to be in the range of nanotechnology products (0 to 100 nm in diameter). This size of the fruit beverage emulsion particles overlaps with the size of the micelles formed in the digestion of fat and therefore are not expected to affect the digestion and absorption of the sucrose monoesters to a large extent.

Sucrose Fatty Acid Ester ADME

The results of an *in vitro* absorption and hydrolysis assay conducted with different sucrose fatty acid esters indicated that only a minimal amount of intact esters are transported across the intestinal tissue and that the mucosal homogenates hydrolyzed approximately 10% and 30% of the sucrose monostearate (SMS) and the sucrose monopalmitate (SMP), respectively, in 10 minutes, while artificial pancreatic juice hydrolyzed roughly 9% and 15% in 30 minutes (Shigeoka, *et al.*, 1984). These results are supported by studies conducted in animals, where following the administration of alcohols containing 1 to 6 alcohol groups including sucrose octaoleate and sucrose monooleate to male rats for a period of 17 days, no fat was absorbed from sucrose octaoleate whereas 100% of the fat was absorbed from sucrose monooleate.

Three fat balance studies were identified in which the metabolic fate of sucrose esters were examined. Daniel *et al.*, (1979) administered ^{14}C sucrose tallowate to male adult CD rats by oral intubation or intraperitoneal (ip) injection at single doses of 5, 50, and 100 mg/kg body weight. Most of the radioactivity was recovered in the expired air (61.5%), urine (5%), and feces (11%) from oral intubation; following ip injection, 61% of the radiolabel was recovered in the urine and 19% in expired air. The low recovery of radioactivity in the urine suggests that the esters were

hydrolyzed to sucrose and fatty acids prior to absorption. Ishizuka and Nakamura (1974), fed a semipurified diet containing 2.5%, 5%, or 10% of sucrose stearate (51% mono, 38% di, and 11% polystearate) to rats for three days and reported that the degree of digestibility was approximately 87% for the monoesters, 34% for the diesters and 18% for the polyesters. In a follow up study, they fed diets containing 2.5% of different sucrose fatty acid esters including lauric, stearic, oleic and behenate acids in addition to tallow esters with varying amounts of monoesters ranging from 72% to 12%. Digestibility correlated to the amount of monoester present. The lauric acid monoester showed a digestibility of 98%, oleic acid esters, 92%, stearic acid esters, 87% and behenic acid esters, 25%.

In studies examining the metabolic fate of stearic acid and palmitic acid in rats, 30 to 67% of an administered dose was excreted in the feces, 11 to 49% was exhaled, and 0.7 to 4.9% was excreted in the urine within 120 hours of administration (Shigeoka, *et al.*, 1984). These results indicate that orally administered sucrose fatty acid esters are hydrolyzed in the intestinal tract to sucrose and fatty acids by esterases found in the intestinal epithelial cells and are subsequently utilized extensively as an energy source. A TLC analysis of the lymph nodes of the rats indicated that no intact sucrose fatty acid esters were found, thus transport from the intestine occurs as the hydrolyzed components, sucrose and fatty acids.

Several studies were identified in which pharmacokinetic parameters were examined following the administration of single doses of relevant compounds (JECFA, 1991). In rats, peak blood concentrations of stearic/palmitic acid compound (S-570) administered as a single oral dose of 50, 100, or 200 mg/kg body weight were reported to occur after 1 hour for the low-dose group and 2 hours for the 2 higher groups, while the half lives of the were observed to be 4.1, 2.4, and 3.1 hours, respectively. The bioavailability of the intact sucrose monoester of stearic acid was extremely low, 0.26 to 0.33%. Peak blood levels were reached 3 hours after the administration of 100 mg/kg body weight of sucrose mono/distearate to rats by oral gavage. After 168 hours post-dose, the excretion for the monostearate in urine, feces and expired air were 2.0%, 35%, and 36%, respectively, with 18% retained in the carcass, and the values were 1%, 67%, and 17%, with 9% retained for the distearate.

In human metabolic studies, only trace levels of sucrose were noted in the urine of 3 volunteers following the consumption of 1 g of sucrose tallowate in a mixture of butter and cream cheese indicating that the sucrose tallowate esters were hydrolyzed prior to absorption (Daniel *et al.*, 1979). Similarly, in a clinical study conducted in 11 healthy male adults, no unchanged mono-, di- or triesters were detected in the urine following consumption of 3 g S-1170, equivalent to approximately 50 mg/kg body weight for a 60 kg person, as a single dose or 2 g taken in two parts in orange juice (JECFA, 1991). Additionally, fecal excretion was between 22 to 31% for low to high single dosed volunteers and 17% for multiple dosed volunteers. These results suggest a hydrolysis rate to sucrose and component fatty acid of 70 to 80%.

Vinyl Fatty Acid Ester Metabolism

A number of *in vitro studies* of the hydrolysis of vinyl fatty acid esters such as vinyl laurate have shown that it is hydrolyzed by purified enzymes including guinea pig pancreatic lipase and human pancreatic lipase (Chahinian *et al.*, 2002). *In vitro* incubation with human or rabbit blood led to the complete saponification of the fatty acid ester (Filov, 1959). Inhalation exposure of rabbits to vinyl fatty acid esters led to the identification of acetaldehyde as a metabolite (Filov, 1959).

Toxicological Studies

Sucrose Fatty Acid Esters

Ishidate *et al.* (1984) evaluated sucrose fatty acid esters in an Ames assay and chromosome aberration assay. No mutagenic effects or chromosomal aberrations were observed following exposure to up to 5.0 mg/plate and 0.036 mg/mL, respectively. In a feed efficiency and growth investigation conducted in Hubbard x Hubbard broilers, the birds were administered diets containing 5% of a sucrose fatty acid ester (SFE)-high monoester (S1670) (75% monoester), a sucrose fatty acid ester-low monoester (S370) (20% monoester), or sucrose, glucose and cellulose (Wei *et al.*, 1984). The low monoester SFE did not significantly alter weight gain, feed efficiency, chick appearance or droppings characteristics, and were overall comparable to the control diets whereas the high monoester SFE significantly altered weight gain. The feed consumption was not measured and the effect was likely due to the poor palability of the diet. A sucrose fatty acid ester, containing 70% stearic acid and 30% palmitic acid with small amounts of oleic acid, was tested in a 13-week subchronic toxicity study and a 2-year carcinogenicity study (28% monoester, 34% diester, 21% triester, 10% tetra and higher esters) (Takeda and Flood, 2002). In the subchronic study, Fischer F344/DuCrj rats were administered diets containing 0, 1%, 3% or 5% of the test substance, corresponding to intakes of 0, 0.67, 1.95 and 3.43 g/kg body weight/day. No deaths were observed in any of the groups. Body weight gain in the male middle-dose group from the beginning to middle part of administration period was reported but this was not considered significant since it was not dose-dependent and was seen in only males. Male middle and high-dose groups had significant increases in albumin and ALT and a significant decrease in absolute kidney weight but these were within the historic control range and not considered toxicologically significant. The test substance was concluded to be non-toxic to the rats at up to 5% in the diet. In the carcinogenicity study, the same strain of rat was exposed to the same levels, but with 50 rats/sex/group (Takeda and Flood, 2002). Increases in ALT levels were noted in the satellite groups up to 13 weeks but was not observed at 26 weeks or 52 weeks. The no-observed adverse effects level (NOAEL) was equivalent to the 5% diet or 1,970 mg/kg body weight/day, the highest dose tested.

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Lauric Acid

Lauric acid demonstrated no mutagenic activity in assays conducted in *Salmonella* mutagenicity assay in tester strains of TA97, TA98, TA1535, and TA1537 with and without exogenous metabolic activation, and demonstrated anticlastogenic potential when administered to Chinese hamsters also dosed with busulfan (Renner, 1986; Zeiger *et al.*, 1988). In a modified acute toxicity study in mice where the mice consumed the ingredient for three days, the lethal dose of lauric acid was calculated to be >1,238 mg/kg/day (Schafer and Bowles, 1985). When lauric acid was administered to male albino rats at up 10.0 g/kg body weight, one death was reported and transient signs of toxicity, including oily and unkempt fur, excessive salivation, mucoid diarrhea, sero-sanguineous discharge from the muzzle and eyes, and depressed righting and placement reflexes, were observed in rats administered 4.64 and 10.0 g/kg body weight (CIR, 1987). Fitzhugh *et al.* (1960) tested lauric acid and various derivatives, including a mixture of mono-, di-, and triglycerides of lauric acid in an Osborne-Mendel strain of albino rats. Five male rats were fed lauric acid at 10% (6,000 mg/kg body weight/day) of their diet for 18 weeks and no observable adverse, clinical or histopathological effects, including altered weight gain or mortality were seen. The results of a chronic toxicity study conducted in Osborne-Mendel albino rats indicate that lauric acid is not considered toxic when administered orally at 25% of the diet for 2 years (Fitzhugh *et al.*, 1960).

Acetaldehyde

The potential toxicity of acetaldehyde was examined in weanling SPF-bred rats in a subchronic toxicity study of 4 weeks in duration in which the rats were administered 25, 125, or 675 mg acetaldehyde/kg body weight/day in drinking water (Til *et al.*, 1988). No deaths were reported and all rats appeared healthy throughout the study. No differences in body weight or food intake were noted in male and female rats administered acetaldehyde compared to their respective controls. Liquid intake was reported to be significantly lower in the top dose group of the acetaldehyde-treated male and female rats. The growth of the water restricted male rat group was significantly lower compared to the control. The relative organ weights (*e.g.*, gonads, brain, heart, kidneys, and liver) of acetaldehyde-treated rats were reported to be unaffected by the treatment; however, the kidney weight of the females in the water-restricted group was reported to be significantly higher than the control group. Slight but significant changes were reported in urinary and plasma parameters in treated male and female rats in the highest dose group. Slight hyperkeratosis observed in the forestomach of animals in this group led the authors to conclude that the no-observed-adverse-effect level (NOAEL) of acetaldehyde was 125 mg/kg body weight/day.

The exposure to sucrose fatty acid esters from fruit flavored drinks for the general population is estimated to be 63.71 mg/day and the maximum level of acetaldehyde in these products is 49.29 ppm and therefore the exposure to acetaldehyde is trivial, equivalent to 0.052 µg/kg body

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weight/day (3.14 µg/60 kg individual/day). The exposure to acetaldehyde that might arise from impurities in the individual fatty acids would also be trivial.

Hydroquinone Methyl Ether (MEHQ) (p-methoxyphenol)(p-hydroxyanisole)

Wada *et al.*, (1990) administered 4-methoxyphenol to young male F344 rats (6 weeks of age) (10 rats/group) (5/cage) in a chow diet at levels of 0, 0.25, 0.5, 1.0, and 2.0 % corresponding to doses of 0, 0.09, 0.2, 0.35, and 0.76 g/kg body weight/day for 51 weeks. Dose dependent reduction in weight gain was observed in final body weights of the treated animals as well as a dose dependent increase in relative liver and kidney weights. Animals treated with the highest dose of p-methoxyphenol developed forestomach ulcers. Mild hyperplasia was noted in all but the lowest dosage group. The NOAEL was equivalent to the lowest dose tested or 0.09 g/kg body weight/day. Asakawa *et al.*, (1994) conducted a chronic toxicity study in which young male and female rats were administered 4-methoxyphenol as 0 (control) or 2% of a chow diet for a period of 104 weeks. Food and water consumption were slightly lower in the treatment group than in the control group. Body weights were significantly reduced in both sexes compared to the control group, while relative liver and kidney weight increases also were noted in both sexes. Gross necropsy revealed multiple nodules or masses in the forestomachs at the mid-region where ring shaped ulceration had been observed at early stages of treatment. No other organs revealed increased incidence of tumorous lesions. In a second chronic toxicity study, Hirose *et al.*, (1997) administered 4-methoxyphenol to young male F344 rats in a chow diet at levels of 0 and 0.4% for 104 weeks. In a separate experiment, groups (10 to 15 rats/group) of young male F344 rats were fed chow diets comprising 0, 0.08, or 0.4% 4-methoxyphenol for 28 weeks following initiation with a series of initiators, DEN, MNU, BBN, and DHPH. No carcinomas were noted in the rats administered 4-methoxyphenol, although forestomach hyperplasia and papilloma were increased to 31% and 12% over the control group, and when the rats were exposed to MNU, the incidence of hyperplasia and papillomas were increased at the higher dose to 87% and 60% respectively. Thus, 4-methoxyphenol was likely a promoter of MNU carcinogenicity as MNU increased forestomach tumors. These findings are not relevant for humans who lack a forestomach.

The exposure to sucrose fatty acid esters from fruit flavored drinks for the general population is estimated to be 63.71 mg/day and the maximum level of p-methoxyphenol in these products is 100 ppb; exposure to p-methoxyphenol is trivial 0.00011 µg/kg (0.00637 µg/60 kg individual).

Human Tolerance Studies

Sucrose Fatty Acid Esters

A human study was conducted in 11 healthy male adult volunteers who received doses of up to 3 g S-1170, a sucrose esters of fatty acids consisting of 57% monoesters, 28% diesters, and 10% triesters of a mixture of stearic and palmitic acid esters in a 70:30 proportion, (equivalent to

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approximately 50 mg/kg body weight for a 60 kg person) as a single dose or 2 g taken in two parts in orange juice. Soft stools were observed in 4/6 subjects consuming 2 g of material, 3/3 subjects consuming 3 g of material but no symptoms were observed following consumption of 1 g daily or 1 g twice daily for 5 days (JECFA, 1991). In groups of male subjects that consumed bread rolls containing 1, 1.5, or 2 g S-1170 at a single meal or 1.5 g S-1170 at 3 meals for 1 or 7 days, or bread rolls containing 1 g S1170 at 2 or 3 meals per day for 5 days no changes in hematology, clinical chemistry or urinalysis were noted. Soft stools were noted in 1/5 subjects consuming 1 dose of 1.5g and in 3/5 subjects consuming 2 g. in the subjects consuming multiple doses of S-1170, increased incidence of soft stools was observed in 4/5 subjects consuming 1.5 g three times daily for 7 days, in 2/5 subjects consuming 1 g three times daily for 5 days, and in 1/5 subjects receiving 1 g two times daily for 5 days. (JECFA, 1991). A double blind cross over study was conducted in 10 men and 10 women, 21 to 35 years who consumed a serving of bread twice daily containing 0.75 g of S-1170 for 5 days followed by a 6 day interval prior to participating in the cross over portion of the study (JECFA, 1997). Mean doses in male subjects were 27 mg/kg and 29 mg/kg in females. Some abdominal symptoms were reported but were not related to treatment. No changes were observed in fecal frequency but soft stools were reported in both treatment and control groups. No changes were reported in the other parameters but since these were measured following the washout period, it was not clear if there were any effects of treatment.

SUMMARY

The sucrose monoesters of lauric acid, palmitic acid and stearic acid generally meet existing specifications of currently available sucrose fatty acid esters although they contain trace levels of additional impurities as a result of their manufacture from vinyl esters of fatty acids. The current intakes of all uses of sucrose fatty acid esters including the uses as emulsifiers of flavor emulsions in fruit flavored beverages approaches 12.6 mg/kg body weight/day in the general population significantly below the current ADI of 30 mg/kg body weight/day. The proposed use from uses as emulsifiers in flavor concentrates used in fruit flavored beverages is a trivial proportion of the total intake, 0.90 mg/kg body weight/day.

The safety of sucrose esters of palmitic acid and stearic acid are supported by metabolism data, subchronic and chronic studies in rats, and tolerance trials in humans, which indicate that only trace amounts of the monomers are absorbed intact. These studies were confirmed with fat balance studies in rodents and humans that indicate hydrolysis of the esters prior to absorption and that essentially 90% of the monoesters are absorbed by this route whereas less absorption of the diesters and higher esters occur. Sucrose fatty acid ester preparations containing mono and higher esters were not mutagenic in the Ames assay nor did they induce chromosomal aberrations in Chinese hamster fibroblasts. Subchronic and chronic studies with sucrose ester preparations containing mono and higher esters up to 5% of the diet or 1970 mg/kg body weight did not produce any toxicologically significant effects. The sucrose fatty acid ester preparations

were well tolerated in human studies although daily doses of two grams and higher were associated with soft stools. JECFA determined an ADI of 30 mg/kg based on physiological effects in humans. The soft stools are caused by the higher sucrose esters that are not hydrolyzed and absorbed. The sucrose monoesters are hydrolyzed to sucrose and fatty acids. Therefore, this ADI is likely not appropriate and the ADI for sucrose monoesters should be much higher.

The safety of sucrose monoester of lauric acid is further supported by safety studies on lauric acid. Lauric acid has a low acute toxicity, is not genotoxic in the Ames assay nor does it cause chromosomal aberrations in Chinese hamsters following gavage at 100 mg/kg body weight. No adverse effects were noted following administration of 6g/kg body weight to rats for 18 weeks or at 25% of the diet for 2 years.

The different manufacturing conditions of sucrose monoesters of fatty acids leads to the presence of small amounts of impurities including vinyl esters of fatty acids, acetaldehyde and p-methoxyphenol that is used as a stabilizer in two of the starting substrates, the vinyl esters. The small residual levels of impurities do not pose health concerns as a result of the trivial amounts that would be consumed from the use of sucrose monoesters as emulsifiers in flavor concentrates used in fruit flavored beverages.

CONCLUSION

We, the Expert Panel, have, independently and collectively, critically evaluated the data and information summarized above and conclude that the proposed uses of sucrose fatty acid monoesters manufactured consistent with current Good Manufacturing Practice (cGMP) and meeting appropriate food-grade specifications as described herein, are safe.

We further conclude that these proposed uses are Generally Recognized as Safe (GRAS) based on scientific procedures.

It is our opinion that other qualified experts would concur with these conclusions.

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01 October 2007
Date

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Attachment 1
Curricula vitae

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CURRICULUM VITAE

NAME

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POSITION/TITLE

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EDUCATION

INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
St. Anselm's College, New Hampshire	B.A.	1964	Biology
University of New Hampshire, Durham, NH	M.S.	1967	Zoology
University of New Hampshire, Durham, NH	Ph.D.	1971	Zoology-Biochemistry

RESEARCH AND PROFESSIONAL EXPERIENCE:

1973-74 Post Doctoral Research Fellow, Masonic Medical Research Laboratory, Utica, NY
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1973-77 Lecturer, Northeastern University of Boston, MA
1973-78 Research Associate in Nutrition, Harvard School of Public Health, Boston, MA
1977-85 Lecturer in Nutrition, Harvard School of Public Health, Boston, MA
1978-82 Assistant Professor of Comparative Pathology, Harvard Medical School, New England
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1982-85 Chairman, Division of Nutrition, Harvard Medical School, New England Regional Primate Research Center,
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1985- Professor, Department of Clinical Sciences, University of Massachusetts-Lowell, Lowell, MA
1991- Research Professor of Medicine, University of Massachusetts Medical School, Worcester, MA
1992- Adjunct Professor, University of Massachusetts Medical School, Worcester, MA
1994- Director, Center for Health & Disease Research, University of Massachusetts-Lowell, Lowell, MA
1998-03 Coordinator, Office of Collaborative Research, University of Massachusetts Lowell, Lowell, MA
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142. **Nicolosi RJ**, Wilson TA, Handelman G, Foxall T, Keaney JF, Vita JA. **Decreased Aortic Early Atherosclerosis in Hypercholesterolemic Hamsters Fed Oil-Rich TriSun Oil Compared to Linoleic Acid-Rich Sunflower Oil.** *J Nutr Biochem*; (2002) 13:392-402.
143. Reece S, **Nicolosi RJ**, Holcroft C, Quattrocchi N, Faul MC. **Asthma in a University Setting: Severity, Impact and Quality of Asthma Care.** *Nurse Practitioner* (2002) 27: 35-42
144. Shea TB, Ekini FJ, Ortiz D, Dawn-Linsley M., Wilson T, **Nicolosi RJ**. **Efficacy of Vitamin E, Phosphatidyl Choline, and Pyruvate on Buffering Neuronal Degeneration and Oxidative Stress in Cultured Cortical Neurons and in Central Nervous Tissue of Apolipoprotein E-deficient mice.** *Free Rad. Bio Med*, (2003) 33: 276-282.

145. Shea TB, Rogers EJ, Ashline D, Ortiz D, Duarte N, Wilson TA, **Nicolosi RJ**. **Vitamin E Deficiency Does Not Induce Compensatory Antioxidant Increases in Central Nervous System Tissue of Apolipoprotein E-deficient Mice.** *J Alzheimer's Dis* (2003) 5:9-14.
146. Shea TB, Ekinci FJ, Ortiz D, Wilson TA, **Nicolosi RJ**. **Efficacy of Vitamin E Phosphatidyl Choline and Pyruvate on ABETA Neurotoxicity in Culture.** *J Nutr, Health Aging* (2003) 7:252-255
147. Wilson TA, Idreis HM, Taylor R, **Nicolosi RJ**. **Whole Fatted Bran Reduces the Development of Early Aortic Atherosclerosis in Hypercholesterolemic Hamsters Compared with Wheat Bran.** *Nutr. Res.* (2002) 22: 1319-1332.
148. Handelman G, Rosales LM, Barbato D, Luscher J, Adhikarla R, **Nicolosi RJ**, Finkelstein FO, Ronco C, Kaysen GA, Hoenich NA, Levin NW. **Breath Ethane in Dialysis Patients and Control Subjects.** *Free Rad Bio & Med* (2003) 35: 1: 17-23.
149. Wilson TA, Foxall T, **Nicolosi RJ**. **Doxazosin, a α -1 Antagonist, Prevents the further progression of the advanced atherosclerotic lesion in Hypercholesterolemic hamsters.** *Metabolism* (2003) 52:1240-1245.
150. Delaney B, **Nicolosi RJ**, Wilson TA, Carlson T, Frazer S, Zheng GH, Hess R, Ostergren K, Haworth J, Knudson N. **Beta-Glucan Fractions from Barley and Oats are Similarly Antiatherogenic in Hypercholesterolemic Syrian Golden Hamsters.** *J Nurt.* (2003) 133:468-495.
151. Yoganathan S, **Nicolosi RJ**, Wilson TA, Handelman G, Scollin P, Tao R, Binford P, Orthofer F. **Antagonism of Croton Oil Inflammation by Topical Emu Oil in CD-1 Mice.** *Lipids* (2003) 38:603 – 607.
152. Hancock AL, Nakuci E, **Nicolosi RJ**, Shea TB. **An Antioxidant Formulation That Induces Differentiation of Neuroblastoma in Culture.** *Neuroscience Research Communications* (2003) 33:73-76
153. Kritchevsky D, Tepper S, Wright S, Czarnecki SK, Wilson TA, **Nicolosi RJ**. **Cholesterol Vehicle in Experimental Atherosclerosis 24: Avocado Oil.** *J Am. Coll. Nutr.* (2003) 22: 52-55
154. **Nicolosi RJ**, Wilson TA, Romano CA, Kritchevsky D. **Dietary Cholesterol is Less Atherogenic Than Saturated Fat in Hamsters with Low Plasma NonHDL- Cholesterol, but More Atherogenic When Plasma NonHDL- Cholesterol is High.** *Nutrition Research* (2003) 23: 299-315.
155. Volicer BJ, Quattrocchi N, **Nicolosi RJ**. **Health and Weight Perceptions of Obese Students.** *Nurse Practitioner* (2003) 28: 13-14.
156. Yoganathan S, **Nicolosi RJ**, Wilson TA, Handelman RJ, Scollin P, Tao R, Binford P, Orthofer F. **Anti-inflammatory Properties of Emu oil in CD-1 Mice.** *Lipids* (2003) 38: 603-607.
157. Binkoski A.E., Kris-Etherton P.M., **Nicolosi RJ**, Wilson T.A. and Blough M.L. **Lipid-Lowering Effects of a Mid-Oleic Sunflower Oil in Moderately Hypercholesterolemic Men and Women.** *FASEB J.* (2003) Abstract 204.4.
158. **Nicolosi RJ**, Wilson T.A., and Delaney B. **Anti-Atherogenic Properties of Beta-Glucans from Barley and Oats in Hypercholesterolemic Syrian Golden Hamsters.** *FASEB J.* (2003) Abstract 204.10.
159. Alexaki A, Wilson TA, Alallah MT, Handelman G, **Nicolosi RJ**. **Hamsters Fed Diets High in Saturated Fat have Increased Cholesterol Accumulation and Cytokine Production in the Aortic Arch Compared with Cholesterol-Fed Hamsters with Moderately Elevated Plasma Non-HDL Cholesterol Concentrations.** *J Nutr.* (2004) 134 (2): 410-415
160. Ockene IS, Chiriboga DE, Stanek EJ, Harmatz MG, **Nicolosi RJ**, Sapiera G, Well AD, Freedson P, Merriam PA, Reed G, Ma Y, Matthews CE, Hebert JR. **Seasonal Variations in Serum Cholesterol: Treatment Implications and Possible Mechanisms.** *Arch of Internal Medicine* (2004) 164:871-879

161. **Nicolosi RJ**, Woolfrey B, Wilson TA, Scollin P, Handelman P, Fisher R. **Decreased Aortic Early Atherosclerosis and Associated Risk Factors in Hypercholesterolemic Hamsters Fed a Diet High or Mid-oleic Acid Oil Compared to High-Linoleic Acid Oil.** *J. Nutr. Biochem* (2004) 15:540-547
162. Wilson TA, **Nicolosi RJ**, Handelman G, Kotyla T, Orthoefer F, Binford P. **Comparative Effects of EMU and Olive Oil on Early Atherosclerosis and Associated Risk Factors in Hypercholesterolemic Hamsters.** *Nutrition Research* (2004) 24: 395-406
163. Wilson TA, **Nicolosi RJ**, Delaney B, Chadwell K, Moolchandani V, Kotyla T, Ponduru S, Zheng G-H, Hess R, Knutson N, Curry L, Kolberg L, Goulson M and Ostergren K. **Comparative Effects of Reduced and High Molecular Weight Barley β -Glucans on Early Atherosclerosis Risk Factors and Aortic Cholesterol Ester Accumulation in Hypercholesterolemic Syrian Golden Hamsters.** *Journal of Nutrition.* (Oct. 2004) 134: 2617-2622
164. Kumar R, Chen M, Parmar VS, Samuelson L, Kumar J, **Nicolosi RJ**, Yoganathan S, Watterson AC. **Supramolecular Assemblies Based on Copolymers of PEG600 and Functionalized Aromatic Diesters for Drug Delivery Applications.** *J. Am. Chem. Soc.* (2004) 126:10640-10644
165. Kritchevsky D, Tepper SA, Wright S, Czarniecki SK, Wilson T, **Nicolosi RJ**. **Conjugated Linoleic Acid (CLA) Isomer Effects in Atherosclerosis: Growth and Regression of Lesions.** *Lipids* July (2004) 39: 311-611
166. Anderson JW, **Nicolosi RJ**, Borzelleca J. **Glucosamine Effects in Humans: A Review of Effects on Glucose Metabolism, Side Effects, Safety Considerations, and Efficacy.** *J Food & Chem Tox* (2005) 43:187-201
167. Watterson AC, Parmar VS, Kumar R, Sharma SK, Tyagi R, Sharma AK, Samuelson LA, Kumar J, Nicolosi RJ, Shea TB. **Indo US Collaborative Studies on Biocatalytic Generation of Novel Molecular Architecture.** *Pur Appl Chem* (2005) 77:201-208.
168. Wilson, T.A., **Nicolosi RJ**, Kotyla, T., Sundrum, K., and Kritchevsky, K. **Different Palm Oil Preparations Reduce Plasma Cholesterol Concentrations and Aortic Cholesterol Accumulation Compared to Coconut Oil in Hypercholesterolemic Hamsters.** *J. Nutr. Biochem* (In Press 2004)
169. Shea TB, Ortiz D, Nicolosi RJ, Kumar R, Watterson AC. **Nanosphere-Mediated Delivery of Vitamin E Increases its Efficacy Against Stress Resulting from Exposure to Amyloid Beta.** (In Press 2005 *J Alzheimer Assoc.*)
170. Yunsheng M, Chiriboga D, Olendzki B, **Nicolosi RJ**, Merriam PA, Ockene IS. **Effect of Soy Protein Containing Isoflavones on Blood Lipids in Moderately Hypercholesterolemic Adults: A Randomized Controlled Trial.** *J Am. College Nutr.* (2005) 24, 4: 275-285

CURRICULUM VITAE

John A. Thomas

WORK HISTORY SUMMARY

- 1961-1982 PROFESSORSHIPS, PHARMACOLOGY & TOXICOLOGY University of Iowa & University of Virginia, Creighton University, and West Virginia University
- 1972-1982 DEANSHIPS, SCHOOL OF MEDICINE, Morgantown, WV Associate Dean, West Virginia University Assistant Dean, West Virginia University
- 1982-1987 VICE PRESIDENT, CORPORATE RESEARCH, BAXTER HEALTHCARE, Deerfield, IL (Multi-National Health Care Corporation)
- 1988-1999 VICE PRESIDENT, ACADEMIC SERVICES University of Texas Health Science Center, San Antonio, Texas (UTHSCSA)
- 1988-Present PROFESSORSHIP, PHARMACOLOGY (Emeritus, 1999) University of Texas Health Science Center, San Antonio, Texas
- 2005-Present ADJUNCT PROFESSOR, Indiana University School of Medicine, Indianapolis, IN.

MILITARY SERVICE

- 1953-1955 Non-commissioned Officer (Sergeant) U.S. Army

EDUCATION

- 1938-1950 La Crosse Public Schools, La Crosse, Wisconsin
- 1951-1953; 1955-56 University of Wisconsin, La Crosse, Wisconsin
- 1956-1961 University of Iowa, Iowa City, Iowa

ACADEMIC DEGREES

- 1956 B.S., University of Wisconsin
- 1958 M A., University of Iowa
- 1961 Ph.D., University of Iowa

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RECENT/CURRENT ACADEMIC APPOINTMENTS

- Professor Emeritus Department of Pharmacology, University of Texas Health Science Center San Antonio, TX
- Professor Department of Obstetrics/Gynecology, University of Texas Health Science Center, San Antonio, TX
- Adjunct Professor Environmental Sciences School of Public Health, University of Texas - Houston
- Clinical Professor Division of Pharmacology & Toxicology College of Pharmacy, University of Texas – Austin, TX

LICENSES AND CERTIFICATES

- 1957 American Registry of Physical Therapists (Inactive)
- 1982-1988 American Academy of Toxicological Sciences - Diplomate
- 1988-1998 American Academy of Toxicological Sciences - Diplomate (re-certified)
- 1997-2002 American Academy of Toxicological Sciences - Diplomate (re-certified)
- 2002-2007 American Academy of Toxicological Sciences – Diplomate (re-certified)

HONORS AND PROFESSIONAL RECOGNITION

- 1960-1966 Dean's Lists, Univ. of Wisconsin - La Crosse; Gamma Alpha, Science Honorary, Univ. of Iowa Pre-doctoral Fellowships, Univ. of Iowa; Foreign Travel Award, American Society for Pharmacology and Experimental Therapeutics, Mexico City, Mexico & Sao Paulo, Brazil
- 1968 Chairman Endocrine Pharmacology, ASPET (University of Minnesota)
- 1971 Chairman, Endocrine Pharmacology, FASEB, (Atlantic City, NJ)
- Visiting Professor and Senior Research Advisor, Faculty of Medicine, University of Ottawa, Ontario, Canada
- McLaughlin Award - Outstanding Teaching Award, West Virginia Univ. School of Medicine (Shared Award)
- Elected Fellow, American School Health Association
- 1973 Co-Chairman, Liver Microsomal Enzymes, Society for Toxicology NY
- 1973-1974 Outstanding Teaching Award, West Virginia University
- 1974 Co-Chairman, Endocrine Pharmacology, ASPET (University of Montreal)
- 1975-1982 Adjunct Professor, Department of Allied Health Sciences, Kent State Univ.
- 1975 Co-Chair, Endocrine Pharmacology, ASPET (University of California-Davis)

HONORS AND PROFESSIONAL RECOGNITION (Cont'd)

- 1977 U.S. Environmental Protection Agency - Certificate of Scientific Service
- 1977 McLaughlin Award - Outstanding Teaching Award, West Virginia University School of Medicine (Shared Award)
- 1978 American Men & Women in Science
- 1978 National Academy of Science Travel Award, XII International Cancer Congress, Buenos Aires, Argentina
- 1978 Maurice O. Graff Distinguished Alumni Award (University of Wisconsin - La Crosse)
- 1980 Co-Organizer, N.I.E.H.S.-Sponsored Target Organ Toxicity: The Endocrines (West Virginia University)
- 1980 Moderator, Environmental Effects on Maturation, Cold Springs Harbor, NY
- 1981 Who's Who in Health Care, 2nd edit.
- 1980-1982 Director, Target Organ Toxicity, Inc., Raleigh, NC
- 1982 Organizer, American Society Pharmacology & Experimental Therapeutics/ Society of Toxicology.- Innovating Models in Teratogenicity (University of Louisville)
- 1983 Organizer, Society of Toxicology, Workshop on Male Reproductive Toxicology, Las Vegas, Nevada
- 1983 Marquis Who's Who (Science & Technology)
- 1984 Co-Recipient, Association of American Publications Award (Technical, Scientific & Scholarly Division). American Journal of Industrial Medicine
- 1984 Secretariat, Scientific Organizing Committee, International Conference on Phthalate Acid Esters, IX IUPHARM Congress, University of Surrey, U.K.
- 1984 Elected Fellow, American Academy of Veterinary Pharmacology & Therapeutics
- 1985 Moderator/Organizer, Monoclonal Antibodies: Their Use in Toxicology & Pharmacology, Society of Toxicology Refresher Course, San Diego, CA
- 1985 Chairman, Male Reproductive Toxicology, American Coll. of Toxicology, Washington, DC
- 1985 Marquis Who's Who in the Midwest, 20th edition
- 1985 Chairman, Plant Biotechnology Consortium Workshop-Pharmaceuticals (Chicago,IL)

HONORS AND PROFESSIONAL RECOGNITION (Cont'd)

- 1985-1987 Councilor, Society of Toxicology
- 1986-1988 Councilor, American College of Toxicology
- 1986 Midwest Toxicology Society, President-elect
- 1986 Chairman, FASEB Symposium, New Drugs Through Biotechnology, St. Louis, MO
- 1986 Organizer, Gordon Conference, Basic Mechanisms of Gonadal Toxins, NH
- 1986 Distinguished Visiting Professor, Depart. of Chemistry, Univ. of Wisconsin, La Crosse, WI
- 1986 Kenneth P. DuBois Award(Outstand. Achieve. Toxicol.), Midwest Reg., Soc. of Toxicology
- 1986-1993 Board of Directors, University of Wisconsin Foundation, La Crosse, WI
- 1987 Vice Chairman, Gordon Conference, Mechanisms of Toxicity, NH
- 1987 Chairman, Society of Toxicology, Symposium on rDNA-Derived Proteins: San Diego, CA
- 1987 Distinguished AMA Lecturer in Medical Sciences, American Medical Assoc., Chicago, IL
- 1987 Co-Chairman, American Chemical Society, Occupational Hazards Symposia, Denver, CO
- 1987 Vice President - Midwest Toxicology Society
- 1988 Chairman, Society of Toxicology, Endocrine Toxicology, Dallas, TX
- 1988 President - Midwest Toxicology Society
- 1989 Chairman, Gordon Research Conference, Mechanisms of Toxicity, NH
- 1989-1999 Board of Scientific Advisors, Texas Society of Biomedical Research
- 1990 President, American Chem. Society, Sub-Division of Chemical Pathology & Toxicology
- 1990 Fellow, American Academy of Toxicology Sciences
- 1991 Marquis Who's Who in Education
- 1992 Marquis Who's Who, Environmental Registry
- 1994-2000 Trustee, International Life Sciences Institute (ILSI) North America
- 1995 Vice President, American College of Toxicology
- 1995 Russian Academy of Medical Sciences, elected Foreign Member
- 1996 Vice President, Gulf State Chapter, Society of Toxicology
- 1997 Honorary Member, Scientific Council, Moscow Medical & Stomatological Instit.
- 1996 President-elect, American College of Toxicology

HONORS AND PROFESSIONAL RECOGNITION (Cont'd)

- 1996 - 2001 Board of Directors, Academy of Toxicological Sciences
- 1997 President, American College of Toxicology
- 1997 Distinguished Alumni Award-Achievement, University of Iowa, Iowa City, IA.
- 1997 Vice President, Texas Society for Biomedical Research
- 1997 - 2002 Member, Expert Advisory Panel, Canadian Network of Toxicology Centers
- 1998 -1999 President, Gulf State Chapter, Society of Toxicology
- 1998 Merit Award (Distinguished Career), Society of Toxicology
- 1999 Marquis Who's Who in Medicine & Healthcare, 2nd, 3rd, 4th, 5th, 6th & 7th edit
- 1999 Distinguished Service Award, American College of Toxicology
- 1999 Vice President, Academy of Toxicological Sciences
- 2000 President, Academy of Toxicological Sciences
- 2001-2003 Marquis' Who's Who in the South and Southeast, 31st edit.
- 2002 Recipient, Hall of Excellence Award, LaCrosse, WI
- 2003 Fellow, American College of Toxicology
- 2004 Marquis Who's Who in America, 59th, 60th & 61st editions
- 2005 Marquis Who's Who in Science & Engineering, 8th edit.
- 2006 FDA Commission's Special Citation
- 2007 FDA Advisory Committee Service Award

PROFESSIONAL SOCIETY COMMITTEES

1973-1983 Amer. Soc. Pharmacol & Exper. Therapy (ASPET), Comm. on Environ. Pharmacol.
1980-1982 ASPET - Section on Toxicology
1982-1983 Society of Toxicology, Education Committee
1985 Awards Committee, ASPET
1986-1988 Program Committee, American College of Toxicology
1988-1991 Executive Committee, ASPET - Section on Toxicology
1993 Program Committee, Society for Basic Urologic Research
1993 Chair, Environmental & Toxic Exposures in Epidemiology of Neural Tube Defects, International Conf. on Neural Tube Defects, U.S-Mexico
1993-1997 Member, National Library of Medicine (LSTRC)
1993-1994 International Conference on Neural Tube Defects, Organizing Committee, Harlingen, TX
1994-1997 Executive Committee, Division of Toxicology, ASPET.
1993-2000 Trustee, International Life Sciences Institute (ILSI) N.A.
1997-Present Publication's Committee, American College of Toxicology
1997-2000 Chair, Expert Advisory Panel, Canadian Network Toxicology Centers
1998 Vice-Chairman, Scientific Program, International Life Sciences Institute (ILSI)
1999 Chairman, Scientific Program, International Life Sciences Institute (ILSI)
1998-2000 Education Committee, Society of Toxicology (Chair, 2000)
1998 Member, American Conference of Governmental Industrial Hygienists
1999-2004 Member, IOM/NAS, Subcommittee on Micronutrients, Re-appointed, 2002-04
2003 -2006 Member, U.S. Air Force Science Advisory Panel, Wash. DC
2003-2007 Member, U.S. FDA, Science Advisory Board, Wash. DC
2007-Present Member, Committee on Toxicology, NRC/NAS
2007 Member, Sub-Comm. FDA Review of NARMS
2007 Member, FDA Science Review –Sub-Comm., Chrm, NCTR

RESEARCH APPOINTMENTS

- 1958-1959 Research Associate, University of Iowa
- 1982 Visiting Senior Scientist - Travenol Laboratories, Chicago, IL
- 1982-1988 Research Professor, Department Urology, Northwestern University School of Medicine

TEACHING ASSISTANTSHIPS AND/OR ACADEMIC APPOINTMENTS

- 1960 Teaching Assistant, Department Physiology, School of Medicine, University of Iowa
- 1961 Instructor, Department Physiology, School of Medicine, University of Iowa
- 1961-1964 Assistant Professor, Department Pharmacology, Univ of Virginia School of Medicine
- 1964-1967 Assoc. Professor, Depart. Physiology/ Pharmacology, Creighton Univ. School Medicine
- 1967-1969 Associate Professor, Department Pharmacology, West Virginia Univ. School of Medicine
- 1970 Visiting Professor and Acting Chairman, Department Pharmacology, Pahlavi University School of Medicine, Shiraz, Iran (University of Pennsylvania exchange program)
- 1970-1982 Professor, Depart of Pharmacology & Toxicology, West Virginia Univ. School of Medicine,
- 1982-1988 Instructor (Adjunct), Department Pharmacology, Rush Medical College, Chicago, IL
- 1982-1988 Lecturer (Adjunct), Department Pharmacology and Toxicology, University of Illinois School of Medicine, Chicago, IL
- 1986-1988 Professor (Adjunct), Div. Clinical Pharmacology, Univ. Health Science/Chicago Medical School, North Chicago, IL
- 1982-1991 Professor (Adjunct), Depart. Pharmacology & Toxicology, West Virginia Univ. School of Medicine,
- 1982-1988 Professor (Adjunct), Department of Pharmacology & Toxicology, Northwestern University School of Medicine, Chicago, IL
- 1986-1989 Clinical Professor (Adjunct), Depart. Preventive Medicine, Medical College of Wisconsin M
- 1988-Present Clinical Professor, University of Texas, School of Pharmacy, Austin, TX
- 1987-Present Adjunct Professor, Department Environmental Sciences, Univ. Texas Health Science Center – Houston, School of Public Health
- 1988-1998 Professor, Department of Pharmacology, University Texas Health Science Center, San Antonio, TX
- 1988-1998 Professor, Department Obstetrics/Gynecology, University of Texas Health Science Center, San Antonio, TX

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1999- Professor (Emeritus), Department of Pharmacology, University of Texas Health Science Center, San Antonio, TX

RESEARCH ACTIVITIES/INTERESTS

- Prostate Biochemistry/Pathology; Steroid Receptors
- Reproductive System Toxicity
- Drug-Hormone and Drug-Nutrient Interactions
- Toxicology of Industrial Chemicals
- Environmental & Occupational Toxicology
- New Drugs Through Genetic Engineering
- GM-Foods & Their Safety
- Biopharmaceuticals
- Agribiotechnology
- Nutritional Toxicology

ORGANIZATIONS (Past and Present)

- American Society for Pharmacology and Experimental Therapeutics (ASPET)(Retired)
- Endocrine Society (Retired)
- American College of Toxicology
- Society of Toxicology
- Western Pharmacology Society
- Sigma Xi
- National Society for Medical Research
- International Union of Toxicology
- Midwest Pharmacology Society
- Canadian Toxicology Society
- Teratology Society
- Pharmacological Society of Canada
- Gulf Coast Society of Toxicology
- Midwest Society of Toxicology
- National Association Biomedical Research
- Association Academic Health Centers
- American Chemical Society, Division Chemical, Health & Safety
- Texas Society of Biomedical Research
- U.S.-Mexico Border Public Health Association
- Society for Basic Urologic Research
- American Council Government Industrial Hygiene

ADMINISTRATIVE EXPERIENCE

- 1973-1975 Assistant Dean, West Virginia University School of Medicine
- Fiscal & Administrative Officer, West Virginia University School of Medicine
- 1973-1975 Promotion and Tenure, West Virginia University School of Medicine
- 1973-1982 Chief Grants and Contracts Officer, West Virginia School of Medicine
- Affirmative Action Liaison, West Virginia School of Medicine
- Biomedical Research Grant Officer, West Virginia University School of Medicine
- Facilities and Scheduling, West Virginia School of Medicine
- West Virginia University School of Medicine, Executive Faculty
- West Virginia University School of Medicine, Admissions Committee, Vice Chairman
- West Virginia University School of Medicine, Promotions Committee, Chairman
- West Virginia University School of Medicine, Educational Program Committee
- 1973-1982 West Virginia University Medical Center Planning Committee, Chairman
- 1974-1982 West Virginia University School of Medicine, Building Committee, Chairman
- 1974-1982 West Virginia University School of Medicine, Learning Resources Committee

ADMINISTRATIVE EXPERIENCE (Cont'd)

- 1975-1982 Academic Review, West Virginia University School of Medicine
- 1975-1982 Associate Dean, West Virginia University School of Medicine
- 1976 American Association of Medical Colleges Executive Development Program (M.I.T. Sloan School of Management), Boston, MA
- 1976-1982 West Virginia University School of Dentistry, Faculty Council
- 1977-1982 West Virginia University School of Medicine, Financial Aids Committee
- 1978-1982 West Virginia University School of Medicine, Computer Users Committee
- 1978-1982 West Virginia University Hospital-Medical School Liaison Committee
- 1979-1982 National Science Foundation, Chairman-Committee to Stimulate Competitive Research in the State of West Virginia (NSF University - Industry Grant Program)
- 1980-1982 West Virginia University Medical Center (rDNA), Chairman- Biohazards Committee
- 1982-1987 Vice President, Corporate R&D, Baxter Healthcare Corporation, Deerfield, IL
- 1982-1985 Life Sciences Research Laboratories, Planning and Building Committee, Baxter Healthcare Corporation, Deerfield, IL
- 1982-1986 Senior Management Council, Baxter Healthcare Corp. Deerfield, IL
- 1985 Executive College, Quality College, Phillip Crosby Associates, FL
- 1988-1998 Executive Committee, University of Texas Health Science Center at San Antonio (UTHSCSA)
- 1988-1998 Committee on Committees, University of Texas Health Science Center at San Antonio
- 1988-1998 Faculty, Graduate School, University of Texas Health Science Center at San Antonio
- 1988-1998 Executive Council, Medical School, The University of Texas Health Science Center at San Antonio, ex officio
- 1988-1998 Executive Council, Dental School, The University of Texas Health Science Center at San Antonio, ex officio
- 1988-1998 Toxicology Consortium, San Antonio Academic and Research Institutes

SELECTED LIST OF PAST AND PRESENT CONSULTANTSHIPS AND ADVISORY ROLES

- H.E.W. - Health Manpower Branch, Region III, Philadelphia, Pa
- Environmental Protection Agency, Washington, D C.
- National Cancer Institute, Committee on Carcinogenesis, Bethesda, MD
- University Park Press, Baltimore, Maryland
- Mason Research Institute, Worchester, MA
- ASHA-PMA Lecturer on Drug Abuse
- Encyclopedia Britannica, Chicago, IL.
- Editorial Board J. Toxicology & Applied. Pharmacology, 1973-1985; Spec. Edit. 2001-2004
- Editorial Board, J. Toxicology & Environmental Health, 1978-1993
- Editorial Board, Perspectives in Toxicology, Raven Press, New York, New York, 1980
- Editorial Board - Fundamental & Applied Toxicology, 1983-1990
- Editorial Board, Technomics Publishing Company (Health Science Division), 1977-1979
- Editorial Board, Target Organ Toxicity Series, Taylor & Francis, Phil, PA, 1989-Present
- Editor-in-Chief, Journal Toxic Substances, Francis & Taylor Publishers, 1993-1997
- Editor, Emeritus, Toxic Substance Mechanisms Journal, 1998 - 2002
- Editorial Board, Food & Chemical Toxicology, 1993-Present
- Editorial Board, Advances in Pharmacology, 1994-Present
- Ad hoc Reviewer - Journal of Animal Science
- Ad hoc Reviewer - Proceedings Society Experimental Biology and Medicine
- Ad hoc Reviewer - Science
- Ad hoc Reviewer - American J. School Health
- Ad hoc Reviewer - American J. Physiology
- Ad hoc Reviewer - Journal of National Cancer Institute
- Ad hoc Reviewer - The Prostrate
- Ad hoc Reviewer - Andrology
- Ad hoc Reviewer - New England Journal of Medicine
- Ad hoc Reviewer - Toxicology Letters
- Ad hoc Reviewer - Journal Pharmacology & Experimental Therapeutics
- Ad hoc Reviewer - Journal of Reproduction & Fertility
- Ad hoc Reviewer - Cell Biochemistry and Function
- Ad hoc Reviewer - Life Sciences
- Ad hoc Reviewer - Asian Journal of Andrology
- Ad hoc Reviewer - Chinese Journal of Nutrition
- Clinical Pharmacology - Texas Allergy Research Foundation, Houston, TX
- Clement Associates, Inc. Scientific Regulatory Consultants, Washington, DC
- World Health Organization (WHO) - Narcotic Division, Geneva, Switzerland
- National Institute Arthritis, Metabolic, and Digestive Diseases, Bethesda, MD
- Union Carbide Corporation, Danbury, CT
- American Public Health Association, Washington, DC
- Urban & Schwarzenberg Medical Publishers, Baltimore, Maryland
- National Science Foundation - Regulatory Biology Program, Washington, D.C.
- Professional Consultants in Occupational Health, Inc., Bethesda, MD
- National Toxicology Program (NTP), Board of Scientific Counselors, NC
- EXXON Corporation, Newark, NJ
- Syntex Research, Palo Alto, CA
- Bell Laboratories, East Millstone, NJ
- IBM Corporation, White Plains, NY
- Ciba-Geigy Pharmaceuticals, Greensboro, NC
- Department of Defense, Review Panel, Defensive Toxins, Ft. Detrick, MD
- Advisory Board, School of Engineering (Biomaterials), Clemson University, Clemson, SC
- American Medical Association-Drug Evaluation, Chicago, IL
- Advisory Board, John Jay College of Criminal Justice Research & Training Center, CUNY
- National Board of Advisors, University of Arizona College of Pharmacy, Tucson, AS
- NutraSweet, Inc., Deerfield, IL

- Monsanto Company, St. Louis, MO

SELECTED LIST OF PAST AND PRESENT CONSULTANTSHIPS AND ADVISORY ROLES (Cont'd)

- Intermedics, Inc., Freeport, TX
- United Oil Products (UOP), Des Plaines, IL
- Rohm & Haas, Philadelphia, PA
- Editor, The Scientific World (on-line)(Toxicology), 2000 – Present
- Board of Trustees, International Life Sciences Institute-North American, Washington, DC
- Advisory Board, Journal of Environmental & Nutritional Interactions
- Publications Committee, Nutrition Reviews
- Advisory Board, San Antonio Medical Gazette
- Advisory Panel: Center for the Study of Environmental Endocrine Effects, Wash., DC
- Novartis, Geneva, Switzerland
- Gerber (Sandoz), Fremont, MI
- Mead-Johnson, Evansville, IN
- Bristol-Myers Squibb, Evansville, IN
- Osteo Screen, Inc. Board Member, 1997-2006
- International Myco Biologics, Board Member, San Antonio, TX
- Center for Human Reproduction, Washington, DC
- Archer Daniel Midland, Decatur, IL

SELECTED LIST OF PAST AND PRESENT COMMITTEES AND OFFICES

- | | |
|-----------|---|
| 1962-1963 | Secretary - Virginia Academy of Sciences, Medical Sciences |
| 1962-1964 | Research Fellowship Committee, University of Virginia |
| 1964 | President - Virginia Academy of Sciences, Medical Sciences |
| 1965-1967 | Secretary-Treasurer, Society of Sigma Xi - Creighton University, NE |
| 1967-1969 | Curriculum Committee, West Virginia University School of Medicine, Chairman |
| 1967-1973 | Director of Graduate Studies in Pharmacology (WVU)
Co-Director, USPHS Training Grant in Pharmacology (WVU) |
| 1967-1982 | Faculty of Reproductive Physiology, Institute of Biological Sciences (WVU) |
| 1968-1974 | Medical Center Long-Range Planning Committee (WVU) |
| 1968-1975 | Cancer Fellowship and Research (WVU) |
| 1968-1980 | Radiation and Isotope Committee (WVU) |
| 1968-1982 | Thesis Committees (WVU) |
| 1968-1984 | Dissertation Committees (WVU) |
| 1969 | Secretary, Society of Sigma Xi - West Virginia University |
| 1969-1976 | Faculty Senate (WVU) |
| 1969-1973 | Medical School Promotions Committee (WVU), Chairman 1970-1973 |

1969-1973 Medical School Admissions Committee (WVU), Vice Chairman, 1970-1973

SELECTED LIST OF PAST AND PRESENT COMMITTEES AND OFFICES (Cont'd)

- 1970-1971 Faculty Senate Committee (WVU), Membership and Constituencies
- 1970-1975 American School Health Association, Committee on Drug Abuse
- 1970-1978 Faculty Promotions & Tenure Committee, Department of Pharmacology (WVU)
- 1970-1979 Pre-Medical Advisory Group (WVU)
- 1970-1979 Basic Science Administrator, West Virginia University Comprehensive Cancer Center
- 1972-1974 President's (WVU) Task Force Committee on North Central Accreditation
- 1972-1974 Faculty Promotions and Tenure (WVU), School of Pharmacy
- 1972-1974 President's ad hoc Council for West Virginia Univ., Research and Graduate Education
- 1972-1974 Inter-Disciplinary Advisory Committee - Masters Program in Nursing (WVU)
- 1975 Graduate Faculty, Kent State University, OH
- 1975; 1991 Board of Examiners, University of Madras, India
- 1975 Board of Examiners, University of Ottawa, Canada
- 1978 Search Committee, University Comptroller (WVU), Chairman
- 1977-1978 Research Strategy Committee (WVU), Chairman
- 1977-1979 University Energy Committee (WVU)
- 1978 By-Laws Committee, West Virginia University School of Medicine
- 1980-1982 Post-Doctoral Training Grant - Endocrinology (WVU)
- 1982 Technical/Scientific Awards Committee, Baxter Healthcare, R&D
- 1982 Professional Career Planning, Baxter Healthcare, R&D
- 1985 Biotechnology Education Task Force, Center for Occupational Research & Development
- 1986 National Science Foundation, Panel on Industry & Technology
- 1988 Chair, Ad Hoc Committee on Research Contracts, University of Texas System
- 1989 Search Committee, Dean, School of Medicine (UTHSCSA)
- 1989 Southern Association of Colleges and Schools (SACS) Steering Committee. TX
- 1989 Search Committee, Chair, Director for Institutional Review Board (UTHSCSA)
- 1989-1992 Chair, Texas Education Opportunity Plan (TEOP) (UTHSCSA)

SELECTED LIST OF PAST AND PRESENT COMMITTEES AND OFFICES (Cont'd)

- 1988-1998 Academic Computing Committee (UTHSCSA)
- 1988-1998 Committee on Committees (UTHSCSA)
- 1988-1998 Library Committee (UTHSCSA)
- 1988-1998 Educational Resources Advisory Committee (UTHSCSA)
- 1988-1998 Institutional Animal Care & Use Committee (UTHSCSA)
- 1988-1998 International Relations Committee (UTHSCSA)
- 1996-1998 Chair, Conflict of Interest Committee (UTHSCSA)
- 2003 Chair, NTP/NIEHS (EG/PG), CERHR, Washington, D.C
- 2006 Mbr. NTP/NIEHS (Soy Formula/Genistein), CERHR, Washington,D.C.
- 2006- 2007 Mbr., Scientific Advisory Board, Soy Nutrition Institute. St. Louis, MO
- 2006 – Present Mbr., National Academy Science, Committee on Toxicology(AEGLE)

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- Thomas JA: Drugs and Athletes. American Chemical Society National Meeting(Washington, DC), August 26-31, 1990.
- Thomas JA: Nutritional Status: Pharmacologic Responsiveness. Proc. U.S.S.R. Academy Medical Sciences, Institute of Nutrition, (Moscow,Russia), Nov., 1990.

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- Thomas, JA. Childhood Obesity, (ILSI, Brazil) Brazilian Society of Pediatrics(Sao Paulo, Brazil),Nov. 1999.
- Thomas, JA Biotechnology in Food Safety: A Scientific Approach. Latin America Food. Science. & Nutrition Conf. (Campinos,Brazil) Nov. 1999
- Thomas JA. Biotechnology; Current and Future Benefits. ILSI Conf. on Modern Biotechnology (Buenos Aires,Argentina) May, 2000
- Thomas JA. Biotechnology and Health Argentina Medical Society(Buenos Aires, Argentina), May, 2000
- Rowlands, J.C & Thomas, J.A. Safe GMMs – Engineering a Safe Microorganism to Produce a Safe Food Ingredient., Proceedings. IFT Annual Meeting(Chicago,IL), July, 2003
- Thomas, JA : Drug-Nutrient Interactions: Recognizing Pharmacologic Implications. Society of Toxicology (San Diego, CA), March 2006
- Thomas, JA & Mutulka, R.: Foods with Inherent Pharmacologic Properties, IFT Annual Meeting(Chicago,IL),July,2007

Professional Certification

Fellow, Academy of Toxicological Sciences

Professional Affiliations

Societies

- Academy of Toxicological Sciences* **
- American Association for the Advancement of Science
- American Chemical Society
- American College of Toxicology*
- American Society of Pharmacology and Experimental Therapeutics**
(Environmental Pharmacology Committee; Liaison Committee, SOT;
Toxicology Committee)
- Institute of Food Technologists (Professional Member)
- International Society of Regulatory Toxicology and Pharmacology*
(Member of Council)
- Sigma Xi
- Society of Experimental Biology and Medicine*
(Councilor; Program Chairman of Southeastern Section)
- Society for Risk Analysis
- Society of Toxicology* **
(Member and/or Chairman: Awards, Education, Legislative Affairs, Membership,
Nominating Committees; Secretary of the Society, Councilor, and President;
President,
Food Safety Specialty Section)
- Virginia Academy of Science*
(Chairman, Medical Sciences Division)

- * Held elected office
- ** Held appointed office or position

Board of Directors

ILSI (until 2002)

Board of Scientific and Policy Advisors

American Council on Science and Health (until 2000)

Journals

Editor, Food Chemical Toxicology, 1992-

Editorial Board

Environmental Carcinogenesis Reviews, 1981-2000
Journal of Environmental Pathology, Toxicology and Oncology 1977- 2000
Journal of Environmental Science and Health, 1979-2004
Journal of the American College of Toxicology, 1982-
Journal of Toxicology: Cutaneous and Ocular Toxicology, 1982- 1992
Journal of Applied Toxicology, 1989-
Pharmacology, 1978-
Pharmacology and Drug Development, 1980-
Toxicology and Applied Pharmacology, 1975-1978

Consultantships (Past, Present)Governmental

Food and Drug Administration
National Institute of Mental Health
National Cancer Institute
Environmental Protection Agency
Department of Labor - OSHA (Chairman, Carcinogens Standards Committee)
U.S. Army - Research and Development Command

Non-Governmental

National Academy of Sciences - NRC
Committee on Toxicology (Member, Chairman)/Board on Toxicology and
Environmental Health Hazards
Safe Drinking Water Committee
Evaluation of Household Substances Committee (1138 Committee)
Food Protection Committee
Food Additives Survey Committee
Committee on Risk-Based Criteria for Non-RCRA Hazardous Wastes
Committee on Risk Assessment of Flame-Retardant Chemicals
Food Chemicals Codex Committee

Federation of American Societies of Experimental Biology
Select Committee on GRAS Substances
Flavors and Extracts
Biotechnology Product Safety
Caprenin GRAS Committee

World Health Organization
Joint Meeting on Pesticide Residues (JMPR) (Member, Chairman)

NATO/CCMS Drinking Water Committee

Industrial

Chemical Companies; Trade Associations

University Activities

Related to Instruction

- Prepared a laboratory manual in pharmacology (animal and human studies) (1960)
- Introduced the use of closed circuit TV and TV tapes in pharmacology (1960)
- Introduced clinical pharmacological experiments into the medical and dental programs (1960)
- Planning and participation in continuing education program (Schools of Dentistry, Medicine and Pharmacy)
- Planning and administration: each of the three major efforts in pharmacology (dental, medical, pharmacy) since 1960.
- Graduate Program - assisted in developing graduate training program in toxicology

Current Teaching Activities

- Present lectures on Toxicological Issues, Food Intake and Control

Not Directly Related to Instruction

- Elected senator from the graduate school, then vice-president of the University Senate
- Served on various committees (e.g. Curriculum, Search, Animal Care,) in each of the four major schools (Dentistry, Graduate, Medical, Pharmacy)

Research

Research was continuously funded from 1956. Sources of support included governmental (U.S.P.H.S.; N.I.H; E.P.A.; N.I.D.A.) and non-governmental (industrial). (A list of publications is attached).

Awards

DOD - US Army - Chemical Research Development and Engineering Center
Distinguished Service Award, 1986

National Italian - American Foundation Award
Excellence in Medicine and Community Service, 1987

Thomas Jefferson University
Distinguished Alumnus Award, 1987

Virginia Commonwealth University - School of Basic Health Sciences
Outstanding Faculty Award, 1987

Virginia Commonwealth University, Dept. of Pharmacology and Toxicology
Professor of the Year- 1992

American College of Toxicology
Distinguished Service Award - 1997

Virginia's Life Achievement in Science Award- April 2001

Bernard L. Oser Food Ingredient Safety Award by the Institute of Food Technologists-
June 2001

International Society for Regulatory Toxicology and Pharmacology's International
Achievement Award for 2001- December 2001

Society of Toxicology - Education Award- March 2002

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- Borzelleca, J.F.: Drug absorption from the urinary tract of the rat. Nicotine. Arch. Int. Pharmacodyn. Ther. 143: 595, 1963.
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- Wooles, W.R., Borzelleca, J.F. and Branham, G.W.: The effects of acute and prolonged salicylate administration on liver and plasma triglyceride levels and dietary-induced hypercholesterolemia. *Toxicol. Appl. Pharmacol.* 10: 1, 1967.
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- Simon, G.S., Tardiff, R.G. and Borzelleca, J.F.: Potential mutagenic and adverse male reproductive effects of 1,2,3,4-tetrabromobutane. A dominant lethal study in the rat. Toxicol. Appl. Pharmacol. 44: 661, 1978.
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- Larson, P.S., Egle, J.L., Jr., Hennigar, G.R. and Borzelleca, J.F.: Acute and subchronic toxicity of mirex in the rat, dog, and rabbit. Toxicol. Appl. Pharmacol. 49: 271, 1979.
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- Simon, G.S., Kuchar, E.J., Klein, H.H. and Borzelleca, J.F.: Distribution and clearance of pentachloronitrobenzene in chickens. Toxicol. Appl. Pharmacol. 50: 401, 1979.
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- Smith, L.W. and Borzelleca, J.F.: Movement of cadmium in rat submaxillary slices. *Toxicol. Appl. Pharmacol.* 55: 403, 1980.
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- Evaluation of the health aspects of sucrose as a food ingredient. 1976.
- Evaluation of the health aspects of sulfiting agents as food ingredients. 1976.
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Evaluation of the health aspects of hydrogenated soybean oil as a food ingredient.

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Evaluation of the health aspects of tannic acid as a food ingredient. 1977.

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Evaluation of the health aspects of corn silk as a food ingredient. 1977.

Evaluation of the health aspects of bentonite and clay (kaolin) as food ingredients. 1977.

Evaluation of the health aspects of citric acid, sodium citrate, potassium citrate, calcium citrate, ammonium citrate, triethyl citrate, isopropyl citrate, and stearyl citrate as food ingredients. 1977.

Evaluation of the health aspects of lactic acid and calcium lactate as food ingredients. 1978.

Evaluation of the health aspects of calcium pantothenate, sodium pantothenate, and D-pantothenyl alcohol as food ingredients. 1978.

Evaluation of the health aspects of Vitamin B12 as a food ingredient. 1978.

Evaluation of the health aspects of Vitamin D2 and Vitamin D3 as food ingredients. 1978.

Evaluation of the health aspects of caffeine as a food ingredient. 1978.

Evaluation of the health aspects of certain glutamates as food ingredients. 1978.

Contributing authorship on the following publications of the Life Sciences Research Office, Federation of American Societies of Experimental Biology (FASEB):

Evaluation of the health aspects of protein hydrolyzates as food ingredients. 1978.

Evaluation of the health aspects of butylated hydroxyanisole as a food ingredient. 1978.

Evaluation of the health aspects of sodium, potassium, magnesium and zinc gluconates as food ingredients. 1978.

Evaluation of the health aspects of urea as a food ingredient. 1978.

Evaluation of the health aspects of thiamin hydrochloride and thiamin mononitrate as food ingredients. 1978.

Evaluation of the health aspects of biotin as a food ingredient. 1978.

Evaluation of the health aspects of ascorbic acid, sodium ascorbate, calcium ascorbate, erythorbic acid, sodium erythorbate, and ascorbyl palmitate as food ingredients. 1979.

Evaluation of the health aspects of propionic acid, calcium propionate, sodium propionate, dilauryl thiodipropionate, and thiodipropionic acid as food ingredients. 1979.

Evaluation of the health aspects of casein, sodium caseinate, and calcium caseinate as food ingredients. 1979.

Evaluation of the health aspects of nickel as a food ingredient. 1979.

Evaluation of the health aspects of soy protein isolates as food ingredients. 1979.

Evaluation of the health aspects of carotene (B-carotene) as a food ingredient. 1979.

Evaluation of the health aspects of nitrogen, helium, propane, n-butane, isobutane, and nitrous oxide as gases used in foods. 1979.

Evaluation of the health aspects of hydrogen peroxide as a food ingredient. 1979.

Evaluation of the health aspects of riboflavin and riboflavin-5-1-phosphate as food ingredients. 1979.

Evaluation of the health aspects of starch and modified starches as food ingredients. 1979.

Evaluation of the health aspects of carbon dioxide as a food ingredient. 1979.

Evaluation of the health aspects of sodium chloride and potassium chloride as food ingredients. 1979.

Evaluation of the health aspects of certain silicates as food ingredients. 1979.

Evaluation of the health aspects of manganous salts as food ingredients. 1979.

Evaluation of the health aspects of copper gluconate, copper sulfate, and cuprous iodide as food ingredients. 1979.

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Evaluation of the health aspects of potassium acid tartrate, sodium potassium tartrate, sodium tartrate and tartaric acid as food ingredients. 1979.

Evaluation of the health aspects of starter distillate and diacetyl as food ingredients. 1980.

Vitamin A, Vitamin A Acetate, and Vitamin A Palmitate as food ingredients. 1980.

Evaluation of the health aspects of iron and iron salts as food ingredients. 1980.

Evaluation of the health aspects of protein hydrolyzates as food ingredients. 1980.

Evaluation of the health aspects of collagen as a food ingredient. 1981.

Evaluation of the health aspects of methyl polysilicones as food ingredients. 1981.

Evaluation of the health aspects of soya fatty acid amines as food ingredients. 1981.

Evaluation of the health aspects of activated carbon (charcoal) as a food processing aid. 1981.

Evaluation of the health aspects of smoke flavoring solutions and smoked yeast flavoring as food ingredients. 1981.

Evaluation of the health aspects of cornmint oil as a food ingredient. 1981.

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Evaluation of the health aspects of wheat gluten, corn gluten, and zein as food ingredients. 1981.

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Food Additives Survey Committee, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences. National Academy Press, Washington, D.C. 1992

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CAST Issue Paper Number 8, November 1997

Attachment 2
Specifications for Sucrose monoesters

000111

Specification Parameter	Specification Limit	Method
Identification		
A. Presence of fatty acid	Positive	FCC (2003)
B. Presence of carbohydrate	Positive	FCC (2003)
Purity		
Assay	Not less than 92% combined mono, and diesters	FCC (2003)
Monoester content	Not less than 83%	Internal validated HPLC method
Acid value	Not more than 6	FCC (2003)
Free sucrose	Not more than 5%	FCC (2003)
Residue on Ignition	Not more than 2%	FCC (2003)
Lead	Not more than 2 mg/kg	FCC (2003)
Dimethylsulfoxide	Not more than 2 mg/kg	FCC (2003)
Isobutanol	Not more than 10 mg/kg	FCC (2003)

000112

SUBMISSION END

000113