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Dr. Mary D. Ditto
Division of Biotechnology and GRAS Notice Review (HFS-255)
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

ENVIRONMENT

Subject:
GRAS Notification for Sucrose Fatty Acid Esters

Date:
January 31, 2012

Contact:
Mark Jackson

810.225.1947

Email:
mark.jackson@arcadis-us.com

Dear Dr. Ditto:

In accordance with the proposed 21 CFR Section 170.36 (Notification of a claim for exemption based on a GRAS determination published in the Federal Register [62 FR 18939-18964]) and on behalf of our client, Libaeration Ltd., we hereby notify the agency of our determination that sucrose fatty acid esters when used as a surface active agent (i.e. foaming agent) in a foaming alcohol topping are GRAS and are therefore exempt from the premarket clearance requirement applicable to food additives under section 409 of the Food, Drug, and Cosmetic Act.

The specific sucrose fatty acid esters that are the subject of this GRAS Notification are also the subject of GRN 129. Libaeration Ltd. purchases their sucrose fatty acid esters directly from Mitsubishi (the notifier of GRN 129). Per discussions with Dr. Robert Merker of the FDA, because the sucrose fatty acid ester that is the subject of this GRAS notice is the same as that of GRN 129, the relevant chemistry and toxicological information from GRN 129 could be referenced. It was recommended by Dr. Merker when the information was the same, that GRN 129 should just be referenced rather than repeating the information in this notice. As such, when appropriate, information from GRN 129 has been referenced.

A an electronic copy of this cover letter, Form 3667, and the GRAS notification has been enclosed on CD along with a hard copy of all documents with signatures.

If you have any questions regarding this GRAS notice, please do not hesitate to contact me.

Sincerely,

(b) (6)

Mark Jackson
Senior Toxicologist

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[redacted]
Division of
Biotechnology and
GRAS Notice Review

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Sincerely,

(b) (6)

Mark Jackson
Senior Toxicologist

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

GENERALLY RECOGNIZED AS SAFE *(GRAS)* NOTICE

Form Approved: OMB No. 0910-0342; Expiration Date: mm/dd/yyyy
(See last page for OMB Statement)

FDA USE ONLY

GRN NUMBER	DATE OF RECEIPT
ESTIMATED DAILY INTAKE	INTENDED USE FOR INTERNET
NAME FOR INTERNET	
KEYWORDS	

Transmit completed form and attachments electronically via the Electronic Submission Gateway *(see Instructions)*; OR Transmit completed form and attachments in paper format or on physical media to: Office of Food Additive Safety *(HFS-200)*, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835.

PART I – INTRODUCTORY INFORMATION ABOUT THE SUBMISSION

1. Type of Submission *(Check one)*
☒ New ☐ Amendment to GRN No. _____ ☐ Supplement to GRN No. _____

2. ☒ All electronic files included in this submission have been checked and found to be virus free. *(Check box to verify)*

3a. For New Submissions Only: Most recent presubmission meeting *(if any)* with FDA on the subject substance *(yyyy/mm/dd)*: _____

3b. For Amendments or Supplements: Is your amendment or supplement submitted in response to a communication from FDA? *(Check one)* ☐ Yes ☐ No If yes, enter the date of communication *(yyyy/mm/dd)*: _____

PART II – INFORMATION ABOUT THE NOTIFIER

1a. Notifier

Name of Contact Person	Position
See Agent below in Section 1b	

Company *(if applicable)*: Libaeration Ltd

Mailing Address *(number and street)*: Ash Tree Farm, 25 Mill Lane

City	State or Province	Zip Code/Postal Code	Country
Boston	Lincolnshire	PE22 0JE	UK

Telephone Number	Fax Number	E-Mail Address
+44 (0) 1205 760284		

1b. Agent or Attorney *(if applicable)*

Name of Contact Person	Position
Mark Jackson	Senior Toxicologist

Company *(if applicable)*: ARCADIS

Mailing Address *(number and street)*: 10559 Citation Drive

City	State or Province	Zip Code/Postal Code	Country
Brighton	MI	48116	United States

Telephone Number	Fax Number	E-Mail Address
(810) 225-1947		Mark.Jackson@arcadis-us.com

PSC Graphics (301) 443-1090 EF

PART III – GENERAL ADMINISTRATIVE INFORMATION

1. Name of Substance

sucrose fatty acid esters

2. Submission Format: *(Check appropriate box(es))*

☐ Electronic Submission Gateway

☐ Paper

☒ Electronic files on physical media with paper signature page

If applicable give number and type of physical media

3. For paper submissions only:

Number of volumes _____

Total number of pages _____

4. Does this submission incorporate any information in FDA's files by reference? *(Check one)*

☒ Yes *(Proceed to Item 5)* ☐ No *(Proceed to Item 6)*

5. The submission incorporates by reference information from a previous submission to FDA as indicated below *(Check all that apply)*

☒ a) GRAS Notice No. GRN 129

☐ b) GRAS Affirmation Petition No. GRP ____ G _____

☐ c) Food Additive Petition No. FAP _____

☐ d) Food Master File No. FMF _____

☐ e) Other or Additional *(describe or enter information as above)* _____

6. Statutory basis for determination of GRAS status *(Check one)*

☒ Scientific Procedures *(21 CFR 170.30(b))* ☐ Experience based on common use in food *(21 CFR 170.30(c))*

7. Does the submission (including information that you are incorporating by reference) contain information that you view as trade secret or as confidential commercial or financial information?

☐ Yes *(Proceed to Item 8)*

☒ No *(Proceed to Part IV)*

8. Have you designated information in your submission that you view as trade secret or as confidential commercial or financial information *(Check all that apply)*

☐ Yes, see attached Designation of Confidential Information

☐ Yes, information is designated at the place where it occurs in the submission

☐ No

9. Have you attached a redacted copy of some or all of the submission? *(Check one)*

☐ Yes, a redacted copy of the complete submission

☐ Yes, a redacted copy of part(s) of the submission

☐ No

PART IV – INTENDED USE

1. Describe the intended use of the notified substance including the foods in which the substance will be used, the levels of use in such foods, the purpose for which the substance will be used, and any special population that will comsume the substance *(e.g., when a substance would be an ingredient in infant formula, identify infants as a special population).*

Surface active agent (i.e., foaming agent) at a maximum level of 0.2% of foaming alcohol topping (See attached document)

2. Does the intended use of the notified substance include any use in meat, meat food product, poultry product, or egg product? *(Check one)*

☐ Yes ☒ No

PART V – IDENTITY

1. Information about the Identity of the Substance

Name of Substance[1]	Registry Used *(CAS, EC)*[2]	Registry No.	Biological Source *(if applicable)*	Substance Category *(FOR FDA USE ONLY)*
a. Sucrose Fatty Acid Esters	Codex INS Number	473		
b.				
c.				

[1] Include chemical name or common name. Put synonyms *(whether chemical name, other scientific name, or common name)* for each respective item (a - c) in Item 3 of Part V *(synonyms)*

[2] Registry used e.g., CAS *(Chemical Abstracts Service)* and EC *(Refers to Enzyme Commission of the International Union of Biochemistry (IUB), now carried out by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology (IUBMB))*

2. Description

Provide additional information to identify the notified substance*(s)*, which may include chemical formula*(s)*, empirical formula*(s)*, structural formula*(s)*, quantitative composition, characteristic properties *(such as molecular weight(s))*, and general composition of the substance. For substances from biological sources, you should include scientific information sufficient to identify the source *(e.g., genus, species, variety, strain, part of a plant source (such as roots or leaves), and organ or tissue of an animal source)*, and include any known toxicants that could be in the source.

3. Synonyms

Provide as available or relevant:

a. Sucrose esters of fatty acids; sucrose esters; Ryoto Sugar Ester; mono-, di-, and tri-ester of sucrose with edible fatty acids.

b.

c.

DRAFT

PART VI – OTHER ELEMENTS IN YOUR GRAS NOTICE

(check list to help ensure your submission is complete – check all that apply)

- ☐ Any additional information about identity not covered in Part V of this form
- ☐ Method of Manufacture
- ☐ Specifications for food-grade material
- ☒ Information about dietary exposure
- ☐ Information about any self-limiting levels of use *(which may include a statement that the intended use of the notified substance is not-self-limiting)*
- ☐ Use in food before 1958 *(which may include a statement that there is no information about use of the notified substance in food prior to 1958)*
- ☒ Comprehensive discussion of the basis for the determination of GRAS status
- ☐ Bibliography

Other Information

Did you include any other information that you want FDA to consider in evaluating your GRAS notice?

☒ Yes ☐ No

Did you include this other information in the list of attachments?

☒ Yes ☐ No

PART VII – SIGNATURE

1. The undersigned is informing FDA that Tim Staniland *(name of notifier)*

has concluded that the intended use*(s)* of Sucrose Fatty Acid Esters *(name of notified substance)*

described on this form, as discussed in the attached notice, is (are) exempt from the premarket approval requirements of section 409 of the Federal Food, Drug, and Cosmetic Act because the intended use(s) is (are) generally recognized as safe.

2. ☐ _____ *(name of notifier)* agrees to make the data and information that are the basis for the determination of GRAS status available to FDA if FDA asks to see them.

_____ *(name of notifier)* agrees to allow FDA to review and copy these data and information during customary business hours at the following location if FDA asks to do so.

_____ *(address of notifier or other location)*

_____ *(name of notifier)* agrees to send these data and information to FDA if FDA asks to do so.

OR

☒ The complete record that supports the determination of GRAS status is available to FDA in the submitted notice and in GRP No.

--- G ----------
(GRAS Affirmation Petition No.)

3. Signature of Responsible Official, Agent, or Attorney	Printed Name and Title	Date (mm/dd/yyy)
(b) (6)	Mark Jackson	01/31/2012

PART VIII – LIST OF ATTACHMENTS

List your attached files or documents containing your submission, forms, amendments or supplements, and other pertinent information. Clearly identify the attachment with appropriate descriptive file names (or titles for paper documents), preferably as suggested in the guidance associated with this form. Number your attachments consecutively. When submitting paper documents, enter the inclusive page numbers of each portion of the document below.

Attachment Number	Attachment Name	Page Number(s) for Paper Copy Only
	GRASNotice_SucroseFattyAcid Esters.pdf	

DRAFT

OMB Statement: Public reporting burden for this collection of information is estimated to average XX hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer (HFA-710), Rockville, MD 20857. (Please do NOT return the form to this address.) An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Important : If you are sending your submissions in paper please include all printed barcode pages with your completed form 3667.

(b) (5)

(b) (5)

(b) (5)

[redacted]

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Generally Recognized as Safe (GRAS) Notification for Sucrose Fatty Acid Esters

January 2012

(b) (6)

Mark Jackson
Senior Toxicologist

(b) (6)

Laura Fell
Senior Toxicologist

(b) (6)

Kirk Dammeyer
Principal Life Scientist

Generally Recognized as Safe (GRAS) Notification for Sucrose Fatty Acid Esters

Prepared by:
ARCADIS G&M of Michigan, LLC
10559 Citation Drive
Suite 100
Brighton
Michigan 48116
Tel 810 229 8594
Fax 810 229 8837

Our Ref.:
B0063549.0000
Date:
January 2012

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1. GRAS Exemption Claim

Libaeration Ltd has determined through consultation with ARCADIS that sucrose fatty acid esters under the conditions of use, as defined herein, are Generally Recognized as Safe (GRAS) consistent with Section 201(s) of the *Federal Food, Drug, and Cosmetic Act.* The determination that the sucrose fatty acid esters are GRAS under the conditions of use was based on scientific procedures as described in the following sections. Therefore, the use of sucrose fatty acid esters as a surface active agent (i.e., foaming agent) in foaming alcohol toppings as described below is exempt from the requirement of premarket approval.

1.1 Name and Address of Notifier

Tim Staniland
Libaeration Ltd
Ash Tree Farm
25 Mill Lane
Butterwick
Boston
Lincolnshire
PE22 0JE
UK
Phone: +44 (0) 1205 760284

1.2 Common Name of the Notified Substance

The common or usual name of the notified substance is sucrose fatty acid esters.

This is the same sucrose fatty acid ester that was the subject of GRAS Notification 129 (GRN 129). Libaeration Ltd (i.e., the notifier of this GRAS Notification) purchases their sucrose fatty acid product directly from the notifier of GRN 129 (Mitsubishi Chemical Corporation). Per personal communication with Mitsubishi-Kaguku Foods Corporation (2011), the Ryoto Sugar Ester product purchased by Libaeration Ltd is the same as under GRN 129.

1.3 Conditions of Intended Use in Food

As defined under Title 21 of the Code of Federal Regulations (21 CFR) Section 172.859, sucrose fatty acid esters are currently approved for use as emulsifiers in baked goods and baking mixes, coffee and tea with added dairy ingredients or dairy product analogues, confections and frostings, dairy product analogues, frozen dairy

desserts and whipped milk products. They are approved for use as texturizers in biscuit mixes, chewing gum, confections and frostings, and surimi-based fabricated seafood products. In addition, they are approved for use 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.

Sucrose fatty acid esters have also been the subject of two previous GRAS Notifications (129 and 248). Under GRN 129, sucrose fatty acid esters were considered GRAS for use as an emulsifier in carotenoid color preparations used in beverages, crackers, soups, and sauces. Under GRN 248, sucrose fatty acid esters were considered GRAS for use as emulsifiers for preparation of fruit flavor concentrates used in preparation of fruit flavored beverages.

The proposed use of sucrose fatty acid esters that is the subject of this GRAS notification is as a surface active agent (foaming agent) at a maximum level of 0.2% of a foaming alcohol product that will be used as a topping for alcoholic beverages. The alcoholic beverages that would use this foam topping would be mixed drinks, cocktails, or dessert drinks.

1.4 Basis for the GRAS Determination

The determination that sucrose fatty acid esters are GRAS was based on scientific procedures consistent with Section 201(s) of the *Federal Food, Drug, and Cosmetic Act* and described further in Section 3 below.

1.5 Statement of the availability of data and information

Please see GRAS Notification 129 for the availability of data and information. The sucrose fatty acid ester product that is the subject of the GRAS Notification is the same as that presented in GRN 129. A literature search was conducted in November 2011 to determine whether any additional data are available sucrose fatty acid esters that were not included in GRN 129. Based on this literature search, no additional data was identified. Therefore, all data and information used in support of this GRAS affirmation is the same as that presented in GRN 129.

2. Detailed Information about the Identity of the Substance

Name: Sucrose Fatty Acid Esters

Codex INS number: 473

Physical Description: stiff gels, soft solids, or white to slightly grayish white powders

Synonyms: Sucrose esters of fatty acids; sucrose esters; Ryoto Sugar Ester; mono-, di-, and tri-ester of sucrose with edible fatty acids.

Please see GRAS Notification 129 for any additional information on the identity of the substance. The sucrose fatty acid ester product that is the subject of this GRAS Notification is the same as that presented in GRN 129.

3. Detailed Summary of Basis for Notifier's GRAS Determination

The sucrose fatty acid ester that is the subject of this GRAS determination was previously submitted under GRN 129. A literature search was conducted in November 2011 and no additional toxicity data were identified that were not previously presented in GRN 129.

The proposed use of the sucrose fatty acid esters that is the subject of this GRAS Notification is as a surface active agent (foaming agent) at a maximum level of 0.2% of a foaming alcohol product that will be used as a topping for alcoholic beverages. However, while the maximum use level proposed is 0.2%, the typical use level would likely be 0.1%. The typical alcoholic beverages that would use this foam topping would include mixed drinks, cocktails, or dessert drinks. The use of sucrose fatty acid esters as a surface active agent (i.e., foaming agent) allows for the base liqueur to foam when under pressure through a pump system. The consumption of alcoholic beverages containing the foaming alcohol is not expected to be frequent, but rather occasional as outlined below.

According to the USDA's Economic Research Service, the per capita consumption of spirits in the U.S. in 2009 was 1.4 gallons (USDA, 2011). Below is a table of the per capita consumption of spirits in the U.S. since 1990.

Table 1: Per Capita Consumption of Distilled Spirits in the U.S. (USDA, 2011)

Year	Per Capita Consumption (Gallons)
1990	1.5
1991	1.4
1992	1.4
1993	1.3
1994	1.3
1995	1.2
1996	1.2
1997	1.2
1998	1.2
1999	1.2
2000	1.3
2001	1.3
2002	1.3
2003	1.3
2004	1.4
2005	1.4
2006	1.4
2007	1.4
2008	1.4
2009	1.4

In addition, the National Institute on Alcohol Abuse and Alcoholism published their per capita consumption of spirits in the U.S. (National Institute on Alcohol Abuse and Alcoholism, 2009). The per capita consumption since 1990 is summarized in the table below.

Table 2: Per Capita Consumption of Spirits in the U.S. (National Institute on Alcohol Abuse and Alcoholism, 2009)

Year	Per Capita Consumption (Gallons)
1990	0.77
1991	0.71
1992	0.71
1993	0.68
1994	0.65
1995	0.63
1996	0.63
1997	0.62
1998	0.62
1999	0.63
2000	0.65
2001	0.64
2002	0.65
2003	0.67
2004	0.68
2005	0.70
2006	0.71
2007	0.73

In addition, as documented in the World Health Organization's Global Status Report on Alcohol and Death (WHO, 2011), the U.S. the per capita consumption of spirits is 2.65 liters (0.7 gallons). The Nevada Division of Mental Health and Developmental Services published their Substances Abuse Prevention and Treatment Agency 2009 Epidemiologic Profile (Nevada Division of Mental Health and Developmental Services, 2009). As documented in this report, the per capita consumption in the U.S. between 1990 and 2006 was in the range of 0.6 to 0.8 gallons. The U.S. Department of Transportation's (2001) report on Alcohol and Highway Safety indicated that the per capita consumption of spirits in the U.S. was between 0.5 and 1 gallon between 1990 and 1997. Based on the available data, the per capita consumption of spirits in the U.S. ranges between 0.5 and 1.5 gallons. The most recent data from the USDA, which represents an upper bound estimate of the per capita consumption, indicates that the per capita consumption of spirits is 1.4 gallons. Therefore, this estimate will be used to determine the estimated daily intake (EDI) for sucrose fatty acid esters for this end use application.

Of this 1.4 gallon per capita consumption, it is expected that only a fraction is expected to represent the per capita consumption of mixed drinks, cocktails, and dessert drinks. Additional research was conducted to determine the delineation of this per capita consumption of spirits into mixed drinks or cocktails that may utilize a foaming alcohol, including communication with the various regulatory bodies (USDA, CDC, etc.) as well as with various industry groups. Although no published data were identified on the percentage of the per capita consumption of spirits that would be in the form of mixed drinks, cocktails, or dessert drinks, personal communication with the Alcohol Research Group of the Public Health Institute, estimated based on their 2010 data from National Alcohol Surveys, approximately 70% of spirit consumption is in the form of mixed drinks (Alcohol Research Group, 2012).

Although it is expected that a small percentage (likely less than 1%) of all mixed drinks consumed would likely contain the foaming alcohol topping, since no market data is currently available, for purposes of illustrating safety, it will be assumed that 100% of spirit consumption in the form of mixed drinks will contain the foaming alcohol topping. Using these worst case estimates the EDI for sucrose fatty acid esters from this end use is as follows:

A maximum of 0.2% SFAE is used per base liquor. An average of 5 milliliters (5.4 grams) of the foam topping containing the sucrose fatty acid ester (SFAE) is estimated to be used per serving. Using the weight of base liquor of 5.4 grams per serving, approximately 10.8 milligrams (mg) of SFAE is consumed per serving.

Using the upper end of the estimated per capita consumption of spirits in the U.S. of 1.4 gallons and the information from the Alcohol Research Group estimating the percentage of that per capita consumption of spirits in the form of mixed drinks is approximately 70%, the estimated number of servings consumed per person per year is as follows:

1.4 gallons spirits/person-year x 0.7 (70% in the form of mixed drinks) x 128 oz/1 gallon x 1 serving/1.5 oz (assuming worst case that each mixed drink using the alcoholic foam only contains a single shot of alcohol equal to 1.5 oz) is approximately 84 servings/year.

Assuming 84 servings are consumed per year, the EDI for SFAE for this end use is approximately 2.5 mg/person/day (84 servings/year x 10.8 mg/serving x 1 year/365 days).

Assuming the average adult weighs 60 kg, the EDI is equivalent to 0.04 mg/kg-day.

Even when using worst case exposure estimates as outlined above, the EDI of 2.5 mg/person/day is well below the acceptable daily intake (ADI) for sucrose fatty acid esters as detailed in GRN 129 of 25 mg/kg-day or 1500 mg/person/day (approximately 3 orders of magnitude lower).

In addition, the ADI developed by Joint FAO/WHO Expert Committee on Food Additives (JECFA) for sucrose fatty acid esters is 30 mg/kg-day based on the chronic toxicity/carcinogenicity study specifically conducted on the S-570 sucrose fatty acid ester produced by Mitsubishi as documented in GRN 129.

Therefore, based on the comparison of the calculated EDI for SFAE for use as a surface active agent (i.e., foaming agent) in a foaming alcohol topping against the ADI for SFAE as previously documented in GRN 129, this end use can be considered GRAS and as such is exempt from the premarket approval requirements of the Food, Drug, and Cosmetic Act.

4. References

Alcohol Research Group. 2012. Personal communication with William Kerr on the estimated percentage of the per capita consumption of spirits in the U.S. is mixed drinks and cocktails. January 5.

Mitsubishi-Kaguku Foods Corporation. 2011. Personal communication with Yukino Nagai to Tim Staniland of Libaeration on the GRAS status of their Ryoto Sugar Esters purchased by Libaeration. November 2.

National Institute on Alcohol Abuse and Alcoholism. 2009. Apparent per capita ethanol consumption for the United States, 1850-2007. http://www.niaaa.nih.gov/Resources/DatabaseResources/QuickFacts/AlcoholSales/Pages/consum01.aspx

Nevada Division of Mental Health and Developmental Services. 2009. Substance Abuse Prevention and Treatment Agency 2009 Epidemiologic Profile. Page 8.

USDA. 2011. ERS/USDA Data: Food Availability (Per Capita) Data System. U.S. Department of Agriculture Economic Research Service. http://www.ers.usda.gov/data/foodconsumption/FoodAvailspreadsheets.htm

U.S. Department of Transportation. 2001. Alcohol and Highway Safety. A Review of the State of Knowledge. http://www.nhtsa.gov/people/injury/research/alcoholhighway/4_drinking_drivers.htm

U.S. FDA. 2010. U.S. Code of Federal Regulations (CFR). Title 21—Food and Drugs (Food and Drug Administration). U.S. Government Printing Office (GPO); Washington, DC. Available from: http://www.access.gpo.gov/nara/cfr/waisidx_09/21cfrv3_09.html

U.S. Department of Transportation (2001)

WHO. 2011. Global Status Report on Alcohol and Health. http://www.who.int/substance_abuse/publications/global_alcohol_report/msbgsruprofiles.pdf

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Division of
Biotechnology and
GRAS Notice Review

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ENVIRONMENT

Moraima J. Ramos Valle, M.S.
Consumer Safety Officer
Division of Biotechnology and GRAS Notice Review (HFS-255)
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Subject:
GRAS Notification for Sucrose Fatty Acid Esters

Date:
February 14, 2012

Contact:
Mark Jackson

810-225-1947

Email:
mark.jackson@arcadis-us.com

Dear Mr. Ramos Valle:

Based on email communication dated February 14, 2012, a revised statement regarding availability of information is required. In accordance with the proposed 21 CFR Section 170.36 (Notification of a claim for exemption based on a GRAS determination published in the Federal Register [62 FR 18939-18964]), the data and information that are the basis for Libaeration's GRAS determination for sucrose fatty acid esters are available for review and copying by FDA at the offices of ARCADIS U.S., Inc., 10559 Citation Drive, Suite 100 Brighton, MI, 48116. These documents will be sent to FDA upon request.

If you have any additional questions regarding this GRAS notice, please do not hesitate to contact me.

Sincerely,

(b) (6)

Mark Jackson
Senior Toxicologist

Imagine the result

Ramos-Valle, Moraima

From: Jackson, Mark [Mark.Jackson@arcadis-us.com]
Sent: Tuesday, February 14, 2012 10:39 PM
To: Ramos-Valle, Moraima
Subject: RE: GRAS submission
Attachments: Letter regarding availability of information GRAS Notification Sucrose Fatty Acid Esters.pdf

Hello Moraima,

Please find the letter attached. Please let me know if this will meet your needs.

Thank you

Kind regards,

Mark

Mark Jackson | Senior Toxicologist | Mark.Jackson@arcadis-us.com
ARCADIS U.S., Inc. | 10559 Citation Drive, Suite 100 Brighton, MI, 48116
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Please consider the environment before printing this email.

From: Ramos-Valle, Moraima [mailto:Moraima.Ramos-Valle@fda.hhs.gov]
Sent: Tuesday, February 14, 2012 3:32 PM
To: Jackson, Mark
Subject: RE: GRAS submission

Yes.

Thanks

From: Jackson, Mark [mailto:Mark.Jackson@arcadis-us.com]
Sent: Tuesday, February 14, 2012 3:31 PM
To: Ramos-Valle, Moraima
Cc: Farias, Bianca *
Subject: RE: GRAS submission

Thank you Moraima. If I attached a letter in pdf format with my signature to an email to you would that be sufficient?

Thank you

Kind regards,

Mark

From: Ramos-Valle, Moraima [mailto:Moraima.Ramos-Valle@fda.hhs.gov]
Sent: Tuesday, February 14, 2012 3:21 PM
To: Jackson, Mark
Cc: Farias, Bianca *
Subject: RE: GRAS submission

Hi Mr. Jackson,

The availability of the information statement should be enough to make your submission filable, keep in mind that we have not reviewed the rest of the information, this is just a first screening to "make through the door". If you wish you can send me a letter with the statement below and your signature by mail or you can send it electronically.

Thanks,
Moraima

Moraima J. Ramos Valle, M.S.
Consumer Safety Officer
FDA/CFSAN/OFAS/DBGNR
Phone: 240-402-1248
Moraima.Ramos-Valle@fda.hhs.gov

From: Jackson, Mark [mailto:Mark.Jackson@arcadis-us.com]
Sent: Tuesday, February 14, 2012 3:13 PM
To: Ramos-Valle, Moraima
Cc: Farias, Bianca *
Subject: RE: GRAS submission

Hello Moraima,

Thank you for the feedback. I appreciate it.

For the comment below, is the statement incorrect in the notice itself or in the Form 3667 or both?

I assume that this is for Section 1.5 of the GRAS Notice and the statement should be corrected to state:

"The data and information that are the basis for Libaeration's GRAS determination are available for review and copying by FDA at the offices of ARCADIS U.S., Inc., 10559 Citation Drive, Suite 100 Brighton, MI, 48116. These documents will be sent to FDA upon request."

Are there any other issues that you have noticed with the submission or once this is corrected it can be filed for review?

Thank you in advance for your time

Kind regards,

Mark

Mark Jackson | Senior Toxicologist | Mark.Jackson@arcadis-us.com
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From: Ramos-Valle, Moraima [mailto:Moraima.Ramos-Valle@fda.hhs.gov]
Sent: Tuesday, February 14, 2012 2:43 PM
To: Jackson, Mark
Cc: Farias, Bianca *
Subject: GRAS submission

Dear Mr. Jackson,

This email is to inform you of our receipt of Libaeration Ltd. GRAS determination for "sucrose fatty acid esters". After reviewing your submission for filing suitability we noticed that the "Availability of the Information" statement is incorrect. The statement should reflect the language use in the proposed rule and available in the "How to submit a GRAS Notice" webpage. For your convenience I extracted this section from the webpage, please see below.

"A statement that the data and information that are the basis for the notifier's GRAS determination are available for the Food and Drug Administration's (FDA) review and copying at reasonable times at a specific address set out in the notice or will be sent to FDA upon request".

Please feel free to contact me if you have any questions.

Thanks,
Moraima

Moraima J. Ramos Valle, M.S.
Consumer Safety Officer
FDA/CFSAN/OFAS/DBGNR
Phone: 240-402-1248
Moraima.Ramos-Valle@fda.hhs.gov

From: Jackson, Mark [mailto:Mark.Jackson@arcadis-us.com]
Sent: Thursday, January 26, 2012 8:12 AM
To: Merker, Robert I
Subject: RE: GRAS Notification Questions

Good morning Dr. Merker,

Thank you for the link provided below.

I have been reviewing the forms and associated guidance and do have some questions. Do you have some time in the next couple of days to have a quick discussion on these questions.

Here is a list of the questions that I have at this time

1. On form 3667, in section Part 1, 3a, it asks whether there was a pre-submission meeting on the subject of this substance. On the FCN side of things, when there is an official pre-notification consultation, it is actually assigned a PNC number. Is this the same for GRAS Notifications? The question I really have is whether or not the communications that I have had with you constitute a presubmission meeting?
   We have no separate number for presubmission meetings. They are logged into our system. The email and telephone contact does not constitute a presubmission meeting.
2. On form 3667, Part II, if I am the preferred contact person, but not the official notifier, how should that be written on the form. In Appendix 5, they indicate that in Section 1a, under the name of the contact person, you can put "see agent". However, would this be in place of the notifier or in addition to the notifier? I am the

designated agent and contact person for this submission, but I am not technically the notifier so I want to make sure I present this correctly.
Agent seems like to appropriate designation – notifier is the company's inside contact, agent is anyone outside the company.

3. On form 3667, Part IV (intended use), I tried to paste in the proposed use of the substance, but space doesn't seem to allow more than one line. Is there a glitch with this section of the form? Is there a character limit? Can I reference the actual dossier here?
Gosh, we haven't had that issue yet, I would summarize it in the form, if you can, and then break it out in the notice for now – I will notifiy our developer that we may need to expand that section of the form.
4. I plan on submitting the GRAS notice electronically on physical media and tried to download the GRAS foldering structure from Appendix 15, but the link appears broken as I keep getting an error message when I try to download. Is there any other way to get the foldering structure?
I don't know if it will go through our firewall, but I added it as an attachment. The link is fine from here, did you j get it from here (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/RegulatorySubmissions/ucm199174.htm)? Alternatively, you can create your own: a Main folder, Administrative, Incoming Correspondence, and Submission subfolders inside the main folder, and amendment, supplement, and submission form subfolders inside the incoming correspondence subfolder.
5. Also just to confirm that I will be including the appropriate information; as part of the submission, I will be including the completed Form 3667, a cover letter to the FDA, and the actual GRAS dossier that provides the justification for GRAS determination, which includes the previous GRN 129 as an Appendix to the dossier. Throughout this GRAS dossier I have referenced GRN 129 where appropriate. Is there anything else that I am missing?
I don't think so, we would like a printed copy of the signature page of the form along with your CD or DVD. You need not include a copy of GRN 129, just state that you are incorporating it by reference. It is already in our files.

Thank you once again for all of your help

Kind regards,

Mark

From: Merker, Robert I [mailto:Robert.Merker@fda.hhs.gov]
Sent: Wednesday, January 25, 2012 10:00 AM
To: Jackson, Mark
Subject: RE: GRAS Notification Questions

Yes. See our guidance at http://www.fda.gov/foodingrpkgsubmissions
Please include the form if possible. Focus on the common elements and Part VI. Of the guidance specific to GRAS Notices. Let me know if you have questions. It's easier than it looks.

Bob Merker

From: Jackson, Mark [mailto:Mark.Jackson@arcadis-us.com]
Sent: Wednesday, January 25, 2012 9:27 AM
To: Merker, Robert I
Subject: RE: GRAS Notification Questions

Thank you Dr. Merker

From the FDA Guidance, it seems that documentation in triplicate is required? Can this be submitted electronically on CD rather than hard copy in triplicate?

Kind regards,

Mark

From: Merker, Robert I [mailto:Robert.Merker@fda.hhs.gov]
Sent: Tuesday, January 24, 2012 2:27 PM
To: Jackson, Mark
Subject: RE: GRAS Notification Questions

For the moment, I would send it to:

Dr. Mary D. Ditto
Division of Biotechnology and GRAS Notice Review (HFS-255)
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food And Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

From: Jackson, Mark [mailto:Mark.Jackson@arcadis-us.com]
Sent: Tuesday, January 24, 2012 2:08 PM
To: Merker, Robert I
Subject: RE: GRAS Notification Questions

Good afternoon Dr. Merker,

I just wanted to follow up on the question below. Have you had an opportunity to pull the specific address information where the GRAS notice should be sent? Should you be the person the GRAS Notice is addressed to?

Thank you

Kind regards,

Mark

Mark Jackson | Senior Toxicologist | Mark.Jackson@arcadis-us.com
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From: Jackson, Mark
Sent: Thursday, January 19, 2012 9:53 AM
To: 'Merker, Robert I'
Subject: RE: GRAS Notification Questions

Good morning Dr. Merker,

As we have been in discussions regarding this GRAS Notification submission, I would like to address the submission to your attention if that would be acceptable to you.

Can you please provide the specific address that this should be sent to you?

Thank you again for all of your help

Kind regards,

Mark

From: Merker, Robert I [mailto:Robert.Merker@fda.hhs.gov]
Sent: Tuesday, January 10, 2012 12:41 PM
To: Jackson, Mark
Subject: RE: GRAS Notification Questions

Mark,

Try looking at GRAS notice 382 as one example; 326 is another. Let me know if these are helpful.

You can navigate to the inventory easily using the short web address: http://www.fda.gov/grasnoticeinventory.

Bob Merker

From: Jackson, Mark [mailto:Mark.Jackson@arcadis-us.com]
Sent: Tuesday, January 10, 2012 10:57 AM
To: Merker, Robert I
Subject: RE: GRAS Notification Questions

Good morning Dr. Merker,

I just wanted to follow up to see if you have had an opportunity to locate an example GRAS notification that referenced a previous notice for much of the technical information as we had discussed last week?

Thank you again for your help

Kind regards,

Mark

From: Merker, Robert I [mailto:Robert.Merker@fda.hhs.gov]
Sent: Wednesday, January 04, 2012 1:56 PM
To: Jackson, Mark
Subject: RE: GRAS Notification Questions

I'm available at 240-402-1226 or I can call you - your choice.

From: Jackson, Mark [mailto:Mark.Jackson@arcadis-us.com]
Sent: Wednesday, January 04, 2012 1:38 PM
To: Merker, Robert I
Subject: RE: GRAS Notification Questions

Tomorrow at 11:00 will work. What number shall I call?

The questions are pretty straight forward, but it is probably easier to talk through rather than to try and type my questions.

Thank you in advance for your time.

Kind regards,

Mark

From: Merker, Robert I [mailto:Robert.Merker@fda.hhs.gov]
Sent: Wednesday, January 04, 2012 1:32 PM
To: Jackson, Mark
Subject: RE: GRAS Notification Questions

Mark,
I have tomorrow at 11 am available. Next Monday is fairly clear.

What works for you?
Regards,
Bob Merker

From: Jackson, Mark [mailto:Mark.Jackson@arcadis-us.com]
Sent: Tuesday, January 03, 2012 10:33 AM
To: Merker, Robert I
Subject: GRAS Notification Questions

Good morning Dr. Merker,

I hope you had a great holiday and a happy new year.

Do you have some availability this week to have a quick call to discuss a few questions I have on a GRAS submission?

Thank you

Kind regards,

Mark

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From: Merker, Robert I [mailto:Robert.Merker@fda.hhs.gov]
Sent: Tuesday, October 11, 2011 4:04 PM
To: Jackson, Mark
Subject: RE: 21 CFR 172.859

Mark,
There is no requirement for convening a GRAS panel, as long as the conclusion that the use of a substance is GRAS is based on publicly available information that reflects scientific consensus.
The more significant piece would be to include any new, relevant data since the previous GRAS notice and update the exposure assessment to include the new use.

Have I addressed your concerns??

Bob Merker

From: Jackson, Mark [mailto:Mark.Jackson@arcadis-us.com]
Sent: Tuesday, October 11, 2011 10:26 AM
To: Merker, Robert I
Subject: RE: 21 CFR 172.859

Thank you for your response Dr. Merker. Your guidance is greatly appreciated.

Just so I am clear on the potential path forward as you have described below.

One, we would conduct a literature search to verify that all relevant data was included in the previous GRAS affirmation

Two, once the literature search has been conducted, we can put together a GRAS Notice essentially indicating that all information is the same as that submitted under GRN 248. However, the notice would need to include any new references or state that a literature search was conducted and no new data was identified. In addition, we would provide the exposure scenario and EDI from this proposed end use and compare it to the CEDI and ADI as described in GRN 248.

Three, the FDA would then review to make a determination whether or not it met the requirements for being GRAS under the proposed conditions of use.

Also, one point of clarification, only a GRAS notice would need to be submitted to the FDA, correct? A full GRAS panel would not need to be consulted for their input on this particular use before submitting to FDA?

Thank you once again for your input

Kind regards,

Mark

From: Merker, Robert I [mailto:Robert.Merker@fda.hhs.gov]
Sent: Tuesday, October 11, 2011 8:27 AM
To: Jackson, Mark
Subject: RE: 21 CFR 172.859

Dr. Jackson,
My initial consideration is that the existing notice is pretty restricted in terms of intended use (fruit-flavored beverages and beverage concentrates) and would be unlikely to include this intended use. Given that we've already seen a GRAS notice; however, you could submit a new notice, essentially incorporating by reference the previous notice, providing an updating of the literature regarding safety (providing there is anything new or noting that there isn't), and providing the (likely very small, I'm guessing, i.e., de minimis) increase in exposure.
If you have questions, we could talk. I'm free from 3 to 4 pm EDT.

Bob Merker

From: Jackson, Mark [mailto:Mark.Jackson@arcadis-us.com]
Sent: Monday, October 10, 2011 2:49 PM
To: Merker, Robert I
Subject: FW: 21 CFR 172.859

Good afternoon Dr. Merker,

I was referred to you by Dr. Honigfort with any GRAS affirmation questions that I may have.

The specific question that I have is in relation to GRN 248. This affirmation notice under 248 summarizes the safety data/information for sucrose fatty acid esters as well as the current uses and CEDI for these uses. If the same exact additive was being used for an addition use that would likely result in a minor portion of the total CEDI, what are the options available for confirming its FDA compliance?

Would a brand new GRAS affirmation need to be submitted to the FDA for this use?

Or is there a process in place that a more informal evaluation would take place by which the intended end use and exposure calculations are provided and compared against the information in GRN 248?

Would you have a few minutes to discuss over the phone?

Thank you in advance for your time

Thank you

Kind regards,

Mark

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From: Honigfort, Mical [mailto:Mical.Honigfort@fda.hhs.gov]
Sent: Thursday, August 04, 2011 9:29 AM
To: Jackson, Mark
Subject: RE: 21 CFR 172.859

Mark,
Here is the link to the GRAS area of our website: http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/default.htm, where you will find a link to the GRN inventory. The GRNs that may be of interest to you are GRNs 129 and 248. GRN 129 is a follow up to GRN 92 so there may also be information of interest in that notice. If you have further questions about the GRAS Notification Program, please contact Dr. Bob Merker at robert.merker@fda.hhs.gov or 240-402-1226.

Regards,

Mical

From: Jackson, Mark [mailto:Mark.Jackson@arcadis-us.com]
Sent: Tuesday, August 02, 2011 10:44 PM
To: Honigfort, Mical
Subject: RE: 21 CFR 172.859

Would 9:00 am EST work for you on Thursday?

Thank you

Mark

From: Honigfort, Mical [mailto:Mical.Honigfort@fda.hhs.gov]
Sent: Monday, August 01, 2011 8:15 AM
To: Jackson, Mark

Subject: RE: 21 CFR 172.859

I am pretty open on Thursday, so please let me know if there is a time that is good for you.

Mical

From: Jackson, Mark [mailto:Mark.Jackson@arcadis-us.com]
Sent: Sunday, July 31, 2011 2:10 PM
To: Honigfort, Mical
Subject: RE: 21 CFR 172.859

Hello Mical,

Thank you very much for getting back in touch with me. I am going to be out of the office on Monday and Tuesday. Will you be available later this week?

Thank you

Kind regards,

Mark

From: Honigfort, Mical [mailto:Mical.Honigfort@fda.hhs.gov]
Sent: Friday, July 29, 2011 12:32 PM
To: Jackson, Mark
Subject: RE: 21 CFR 172.859

Mark:
Ed forwarded your message to me since it involves a direct food additive. I would be happy to discuss your options with you. Would you have a few minutes next week to discuss? I am available both Monday and Tuesday morning between 9 and 12, if you have time either day.

Regards,

Mical

Mical Honigfort, PhD
Consumer Safety Officer
Division of Petition Review
Office of Food Additive Safety
FDA/CFSAN
240-402-1278

mical.honigfort@fda.hhs.gov

From: Jackson, Mark [mailto:Mark.Jackson@arcadis-us.com]
Sent: Thursday, July 28, 2011 3:35 PM
To: Machuga, Edward J
Subject: 21 CFR 172.859

Good afternoon Dr. Machuga,

We are working with a sucrose fatty acid ester that meets the specifications under 21 CFR 172.859. However, alcohol is not covered under this section. The intended end use would be as a foaming agent in liquor for use as a topping in alcoholic beverages, coffee, ice cream, etc. Essentially, it enables a liquor (such as a chocolate liquor) to be foamed when pumped so that it can be used as a topping. It has been approved for use in Europe for this specific end use, but is not covered under 21 CFR 172.859.

In order to obtain FDA approval for this end use in the U.S., would a full food additive petition need to be submitted, or would it be possible to provide some data to the FDA and an informal review be conducted to get an opinion on whether this end use is safe and appropriate?

Thank you

Kind regards,

Mark

Mark Jackson | Senior Toxicologist | Mark.Jackson@arcadis-us.com

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