NutraSource, Inc.
6309 Morning Dew Ct, Clarksville, MD 21029
(410)-531-3336 or (301) 875-6454

March 25, 2020

Dr. Paulette Gaynor
Division of Biotechnology and GRAS Notice Review
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740

Subject: GRAS Notification –
Docosahexaenoic Acid (DHA)-Rich Oil as a Food Ingredient

Dear Dr. Gaynor,

On behalf of Hubei Fuxing Biotechnology, Co., Ltd (Hubei Fuxing), we are submitting a GRAS notification for docosahexaenoic acid (DHA)-rich oil as a food ingredient. The enclosed document provides the notice of a claim that a food ingredient, the DHA-rich oil, described in the enclosed notification is exempt from the premarket approval requirement of the Federal Food, Drug, and Cosmetic Act because it has been determined to be generally recognized as safe (GRAS), based on scientific procedures, as a food ingredient. We believe that this determination and notification are in compliance with Pursuant to 21 C.F.R. Part 170, subpart E.

Please note that this is a resubmission of GRN 860. The manufacturing process described in this notice is different from those described in other GRAS notices. However, the specifications and composition of Hubei Fuxing's DHA-rich oil are substantially equivalent to those presented in other GRAS notices.

We enclose an original copy of this notification and a CD Rom for your review. Please feel free to contact me if additional information or clarification is needed as you proceed with the review. We would appreciate your kind attention to this matter.

Sincerely,

March 25, 2020

Susan Cho, Ph.D.
Susanscho1@yahoo.com
Agent for Hubei Fuxing Biotechnology, Co., Ltd

THE GENERALLY RECOGNIZED AS SAFE (GRAS) DETERMINATION OF DOCOSAHEXAENOIC ACID (DHA)-RICH OIL AS A FOOD INGREDIENT

Prepared for Hubei Fuxing Biotechnology, Co., Ltd

Prepared by: Susan S. Cho, Ph.D.
NutraSource, Inc.
6309 Morning Dew Court
Clarksville, MD 21029
Tel: 410-531-3336
Susanscho1@yahoo.com

GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF DOCOSAHEXAENOIC ACID (DHA)-RICH OIL AS A FOOD INGREDIENT

Table of contents

Tables

Figures

PART 1. SIGNED STATEMENTS AND A CERTIFICATION

Pursuant to 21 CFR Part 170, subpart E, Hubei Fuxing Biotechnology, Co., Ltd (hereinafter referred to as 'Hubei Fuxing') submits a Generally Recognized as Safe (GRAS) notice and claims that the use of docosahexaenoic acid (DHA)-rich oil in foods, as described in Parts 2 through 7 of this GRAS notice, is not subject to premarket approval requirements of the FD&C Act based on its conclusion that the substance is GRAS under the conditions of its intended use.

1.A. Name and Address of the Notifier

Contact: Rebecca Li
Company: Hubei Fuxing Biotechnology, Co., Ltd
Address: Floor 11th, Bldg. 23, Yinhu Enterprise Zone, Baishazhou Ave., Hongshan District, Hubei Province, China
Tel: +86-18971139417
E-mail: 24711275@qq.com

1.B. Common or Trade Name

Docosahexaenoic acid-rich oil, DHA-rich oil, docosahexaenoic acid-rich algal oil, DHA-rich algal oil, DHA algal oil, or DHA-oil.

1.C. Applicable Conditions of Use of the Notified Substance

1.C.1. Foods in Which the Substance is to be Used

(1) Selected conventional foods

Hubei Fuxing intends for DHA-rich oil to be used in food categories currently listed in 21 CFR 184.1472(a)(3), except in egg, meat, poultry, and fish products (Table 1). These are the same food categories found in the GRAS notifications for algal oil derived from *Schizochytrium* sp. (GRNs 137 and 732) for which the FDA did not raise any questions as to the safety when the intended uses included the food categories identified for menhaden oil. The only difference is that Hubei Fuxing does not intend to use its DHA-rich oil in egg, meat, poultry, and fish products.

(2) Infant formulas

Hubei Fuxing intends for DHA-rich oil, produced from *Schizochytrium* sp., to be used as a food ingredient in exempt (pre-term and/or low birth weight infants; amino acid-, extensively hydrolyzed protein-based) and non-exempt infant formulas (term infants; soy-, whey-, and/or milk-based; ages from birth to 12 months) in combination with a safe and suitable source of arachidonic acid (ARA). Hubei Fuxing's DHA-rich oil will be added to ready-to-drink or powder forms of infant formulas from which reconstituted infant formulas can be prepared.

1.C.2. Levels of Use in Such Foods

Selected Conventional Foods

As shown in Table 1, Hubei Fuxing intends for DHA-rich oil (containing ≥36% DHA) to be used in the same food categories as those listed in GRNs 137 (future intended use levels listed on pages 22-23; stamped page 27-28) and 732 (pages 4-5) and in 21 CFR 184.1472(a)(3) (menhaden oil), except in egg, meat, poultry, and fish products, at maximum use levels that are 27.78% of those specified in 21 CFR 184.1472(a)(3), which was finalized in 2005 (FDA, 2005).

Table 1. Maximum Intended Use Levels of DHA-Rich Oil from *Schizochytrium* sp.[1]

Food category	Maximum use levels, %	
	Menhaden oil 184.1472(a)(3)	Current notice
Baked goods and baking mixes (1)	5.0	1.39
Cereals (4)	4.0	1.11
Cheese products (5)	5.0	1.39
Chewing gum (6)	3.0	0.83
Condiments (8)	5.0	1.39
Confections and frostings (9)	5.0	1.39
Dairy products analog (10)	5.0	1.39
Fats and oils (12) (not including infant formula)	12.0	3.33
Frozen dairy products (20)	5.0	1.39
Gelatins and puddings (22)	1.0	0.28
Gravies and sauces (24)	5.0	1.39
Hard candy (25)	10.0	2.78
Jams and jellies (28)	7.0	1.94
Milk products (31)	5.0	1.39
Nonalcoholic beverages (3)	0.5	0.14
Nut products (32)	5.0	1.39
Pastas (23)	2.0	0.56
Plant protein products (33)	5.0	1.39
Processed fruit juices (35)	1.0	0.28
Processed vegetable juices (36)	1.0	0.28
Snack foods (37)	5.0	1.39
Soft candy (38)	4.0	1.11
Soup mixes (40)	3.0	0.83
Sugar substitutes (42)	10.0	2.78
Sweet sauces, toppings, and syrups (43)	5.0	1.39
White granulated sugar (41)	4.0	1.11

[1]The food categories correspond to those listed in 21 CFR 170.3(n). The number in parenthesis following each food category is the paragraph listing of that food category in 21 CFR 170.3(n).
Intended use has been adopted from GRNs 137 and 732 with the exception of meat, poultry, and fish products.

Infant Formula

Hubei Fuxing's DHA-rich oil may be used at a maximum use level of 1.39% of total dietary fat providing 75 to 93 mg DHA-rich oil/kg bw/day. This level corresponds to a maximum of 0.5% of total dietary fat as DHA because Hubei Fuxing's DHA-rich oil has ≥36% DHA. The ratio of DHA to ARA would range from 1:1 to 1:2. The intended use level is similar to all other approved uses for incorporation of DHA-rich oil in infant formula (GRN 553 - stamped page 12 or page 6; GRN 677 - page 6; GRN 731 - page 5; GRN 776 - page 3; GRN 777 - page 3). Hubei Fuxing's DHA-rich oil will be added to ready-to-drink or powder forms of infant formulas from which reconstituted infant formulas can be prepared.

1.C.3. Purpose for Which the Substance is Used

The substance will be used as an ingredient in selected foods and in non-exempt and exempt infant formulas.

DHA-rich oil is a free flowing, yellow oil. The use of DHA-rich oil in the above described food categories may also incidentally contribute its own color to the product. Its intended use would thus fall outside the definition of "color additive," in accordance with 21 CFR 70.3(f), "Substances capable of imparting a color to a container for foods----are not color additives unless the customary or reasonably foreseeable handling or use of the container may reasonably be expected to result in the transmittal of the color to the contents of the package or any part thereof. Food ingredients...which contribute their own natural color when mixed with other foods are not regarded as *color additives...."*

1.C.4. Description of the Population Expected to Consume the Substance

Selected general food applications - the population expected to consume the substance consists of members of the general population (aged 1 year or older) who consume at least one of the products described above.

Infant formula applications – infants consuming formulas (preterm and/or low birth weight infants as well as full-term infants).

1.D. Basis for the GRAS Determination

This GRAS conclusion is based on scientific procedures in accordance with 21 CFR 170.30(a) and 170.30(b).

1.E. Availability of Information

The data and information that are the basis for this GRAS conclusion will be made available to FDA upon request by contacting Rebecca Li at Hubei Fuxing at the address above. The data and information will be made available to FDA in a form in accordance with that requested under 21 CFR 170.225(c)(7)(ii)(A) or 21 CFR 170.225(c)(7)(ii)(B).

1.F. Availability of FOIA Exemption

None of the data and information in Parts 2 through 7 of this GRAS notice are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. §552.

1.G. Certification

We certify that, to the best of our knowledge, our GRAS notice is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to us and pertinent to the evaluation of the safety and GRAS status of the use of the substance.

1.H Name, Position/Title of Responsible Person Who Signs Dossier, and Signature

Name: Rebecca Li Date: March 25, 2020
Title: Export Manager

Address correspondence to
Rebecca Li
Hubei Fuxing
Floor 11th, Bldg. 23, Yinhu Enterprise Zone, Baishazhou Ave., Hongshan District, Hubei Province, China
Tel: +86-18971139417
Email: 24711275@qq.com

1.I. FSIS/USDA Statement

Hubei Fuxing does not intend to add DHA-rich oil to any meat and/or poultry products that come under USDA jurisdiction. Therefore, 21 CFR 170.270 does not apply.

PART 2. IDENTITY, MANUFACTURING, SPECIFICATIONS, AND TECHNICAL EFFECTS OF DHA

2.A.1. Identity of the Notified Substance

2.A.1.1. Common Name

Docosahexaenoic acid-rich oil, DHA-rich oil, docosahexaenoic acid-rich algal oil, DHA-rich algal oil, DHA algal oil, DHA-oil

2.A.1.2. Chemical Names

Its systematic name is *all-cis*-docosa-4,7,10,13,16,19-hexa-enoic acid, and its shorthand name is 22:6(n-3).

2.A.1.3. Chemical Abstract Service (CAS) Registry Number

6217-54-5

2.A.1.4. Empirical Formula

Molecular formula, $C_{22}H_{32}O_2$

2.A.1.5. Molecular Weight

328.488

2.A.1.6. Structural Formula

Figure 1 shows the structure of DHA.

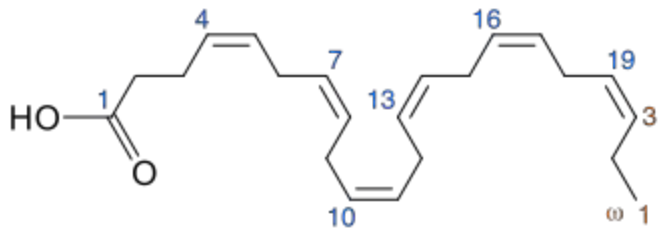


Figure 1. Structure of DHA

2.A.1.7. Physical Properties

Density, 0.943 g/cm^3

2.A.1.8. Background

Docosahexaenoic acid (DHA) is a long-chain polyunsaturated fatty acids (LCPUFA) that is a primary structural component of the human brain, retina, and other tissues. DHA's structure is a 22-carbon chain carboxylic acid with six *cis*-double bonds; the first double bond is located at the third carbon from the omega end (methyl terminus). Thus, it is classified as an omega-3 fatty

acid. It can be synthesized from alpha-linolenic acid or obtained directly from maternal milk, algal oil, or fish oil.

Hubei Fuxing's DHA-rich oil is derived from the heterotrophic fermentation of the marine alga, *Schizochytrium* sp. strain DHF.

2.A.2. Potential Toxicants in the Source of the Notified Substance

Potential toxicants have not been identified in Hubei Fuxing's DHA-rich oil. Hubei Fuxing's DHA-rich oil is ≥36.0% pure with an average of 38.9%. The Certificates of Analysis (COA) for DHA-rich oil are presented in Appendix A.

Shellfish Poison and Mycotoxins

No amnesic shellfish poison (domoic acid) and mycotoxins (fumonisins, aflatoxins, vomitoxin, zearalenone, or ochratoxin A) were detected in Hubei Fuxing's DHA-rich oil (Tables 2 and 3; Appendix A).

Because the manufacturing process involves the fermentation of glucose with yeast extracts and mineral sources by *Schizochytrium* sp. and does not employ any organic solvents, it is not expected to have any significant amounts of dioxins and furans, polychlorinated biphenyls (PCBs), polycyclic aromatic hydrocarbons (PAHs), or solvent residues in the finished DHA-rich oil ingredient (Appendix A).

Table 2. Analytical Results for Amnesic Shellfish Poison

Amnesic Shellfish Poison, Domoic Acid*, ug/g	D1807 1101J	D1808 1801J	D1811 1401J	D1812 2601J	D1912 2101D
Detection limit	< 3.0	< 3.0	< 3.0	< 3.0	<3.0
Results	ND	ND	ND	ND	ND

*Domoic acid was analyzed by a validated Eurofins' internal LC/MS method.

Table 3. Analysis of Mycotoxins for DHA-Rich Oil

Parameters, µg/kg	Lot Numbers					LOQ
	D1807 1101J	D1808 1801J	D1811 1401J	D1812 2601J	D1912 2101D	
Fumonisin (B1+B2+B3)	<30	<30	<30	<30	<30	<30
Fumonisin B1	<10	<10	<10	<10	<10	<10
Fumonisin B2	<10	<10	<10	<10	<10	<10
Fumonisin B3	<10	<10	<10	<10	<10	<10
Aflatoxin B1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Aflatoxin B2	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Aflatoxin G1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Aflatoxin G2	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Sum of all positive Aflatoxins	<0.4	<0.4	<0.4	<0.4	<0.4	

Zearalenone	<25	<25	<25	<25	<5.0	<25
Vomitoxin	<50	<50	<50	<50	<10	<50
Ochratoxin A	<1	<1	<1	<1	<5.0	<1

LOQ=limit of quantitation; The data were provided by Eurofins based on validated internal methods: IAC-LC-MSMS (JAOAC 92 [2], 496) for fumonisins, an Eurofins' method based on EN14123 for aflatoxins, a LC-MSMS method (Food Addt Contamin Part A, 2013:30(3):541-9) for zearalenone and vomitoxin, and AOAC 2000.16 for ochratoxin A.

2.A.3. Particle Size

DHA-rich oil – Not applicable.

2.B. Method of Manufacture

Fermentation

The sterilized culture flask is inoculated with a non-toxigenic, non-pathogenic *Schizochytrium* sp. strain DHF and shaken at 26 ± 4°C for 48 to 72 hours. The pH is adjusted with sodium hydroxide or citric acid. The culture flasks are transferred to the first seed tank and then subsequently scaled up in a series of seed tanks. The fermentation medium contains yeast extract, glucose, and mineral sources.

Purification

After fermentation, the pH is adjusted to 8-9 with sodium hydroxide, and then the cell wall is hydrolyzed for 2 to 4 hours by alkaline protease (Novozyme Alcalase, 2.4 AU/mL). The crude DHA-rich oil is separated from the fermentation biomass by disc centrifuge. The oil is then subjected to degumming (citric acid, disodium ethylenediaminetetraacetate [EDTA], and water), deacidification (sodium hydroxide), washing with water, decolorization (nitrogen, activated carbon, and activated clay at 70 to 90°C for 45 to 60 minutes), filtration at 60 to 70°C, and deodorization (at 190 to 210°C and -230 pa for 1.5 to 3.5 hours). Alkaline protease is deactivated during the decolorization/deodorization processes at high temperature.

Packaging

After cooling to 70-90°C in a temporary tank, nitrogen, tocopherols (0.2%), and ascorbyl palmitate (0.05%) are added to the oil. The refined oil is placed into aluminum drums and stored after quality control (QC) testing.

All raw materials and processing aids used in the fermentation and manufacturing processes meet internationally recognized specification requirements for food production. Hubei Fuxing observes the principles of Hazard Analysis Critical Control Point (HACCP)-controlled manufacturing process and current good manufacturing practices (cGMP) and rigorously tests its final production batches to verify adherence to quality control specifications. Critical control points are monitored to detect insufficient controls on the process (such as incomplete sterilization, incorrect pH or temperature ranges, insufficient fatty acid composition, etc.). If any of those control characteristics fail to meet internal specifications, the fermentation is terminated and the batch rejected. Contamination checks also are conducted in the seed and production

fermenter. All finished batches of DHA-rich oil undergo rigorous quality assurance testing to meet product specifications prior to release.

Tables 4 and 5 present the regulatory status of raw materials used in fermentation and processing aids.

Table 4. Raw Materials Used in Fermentation

Ingredient	Regulatory status
Yeast extract	21 CFR 172.896
Glucose	21 CFR 168.110; 184.1857
Magnesium sulfate (heptahydrate)	21 CFR 184.1443
Potassium dihydrogen phosphate	No CFR citation *
Sodium chloride	21 CFR 182.1(a)
Calcium chloride	21 CFR 184.1193
Sodium hydroxide	21 CFR 184.1763

*FDA did not object to the substitution of K for Na for potassium chloride and potassium sulfate. Sodium phosphate-21 CFR 182.1778.

Table 5. Processing Aids

Processing aids	Regulatory status
Tocopherols	21 CFR 182.3890
Bentonite - Activated clay	21 CFR 184.1155
Activated carbon	No CFR citation *
Ascorbyl palmitate	21 CFR 182.3149
Citric acid monohydrate	21 CFR 184.1033
Sodium hydroxide	21 CFR 184.1763
Disodium EDTA	No CFR citation for the intended use**
Nitrogen	21 CFR 184.1540
Protease enzyme preparation	21 CFR 184.1027

* Meets the requirements of the latest version of the Food Chemical Codex (FCC 11th and 12th ed).
**Disodium EDTA is allowed for use in dressings, sauces, and other foods (21 CFR 172.135).

Figure 2 presents the manufacturing flow diagram of DHA-rich oil.

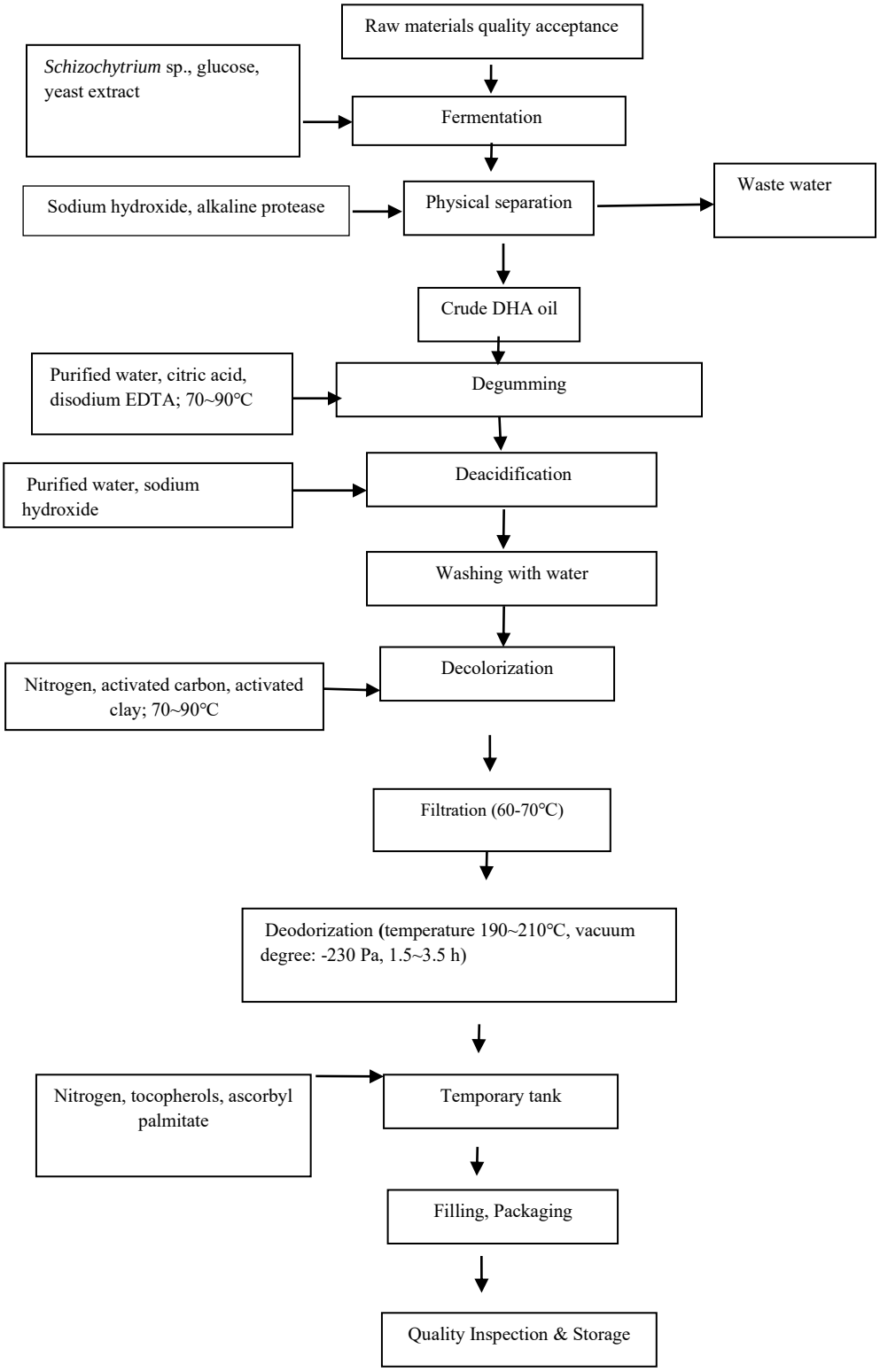


Figure 2. Manufacturing Flow Diagram of DHA-Rich Oil

Characterization of the Production Microorganism

The production method (algal fermentation) is similar to those described by other companies whose production methods for DHA-rich oils received 'no objections' letters from the FDA (GRN 137 - FDA, 2004; GRN 553 - FDA, 2015; GRN 677 -FDA, 2017; GRN 731/732 - FDA, 2018a, 2018b; GRN 776/777 - FDA, 2018c, 2018d). DHA-rich algal oils are derived from the heterotrophic fermentation of the marine alga, a non-toxigenic and non-pathogenic strain of *Schizochytrium* sp. Based on the morphology and 18S rRNA gene sequence analysis, the China Center for Type Culture Collection (CCTCC) identified Hubei Fuxing's strain DHF as *Schizochytrium* sp. (Appendix B). *Schizochytrium* sp. is a thraustochytrid and a member of the Chromista kingdom. There are no reports of this organism producing toxic chemicals or being pathogenic. Consumption by man of thraustochytrids, especially those of the genus *Schizochytrium*, is primarily through the consumption of mussels and clams. Indirect consumption, through the marine food chain (fish and shellfish), is more widespread. Analysis of the finished DHA-rich oil ingredient confirmed the absence of common shellfish toxins. The taxonomic classification of *Schizochytrium* sp. is presented in Table 6.

Table 6. Taxonomic Classification of *Schizochytrium* sp.

Class	Scientific Classification
Kingdom	Chromista
Subkingdom	Harosa
Phylum	Bigyra
Subphylum	Sagenista
Class	Labyrinthulea
Order	Thraustochytrida
Family	Thraustochytriaceae
Genus	*Schizochytrium* sp.
Strain	*Schizochytrium* sp. DHF

2.C. Specifications and Composition

The safety of DHA-rich oils derived from *Schizochytrium* sp. was evaluated in humans, animals, and/or mutagenicity/genotoxicity studies by many research groups (Falk et al., 2017; Fedorova-Dahms et al., 2011a, 2011b; Lewis et al., 2016; Schmitt et al., 2012a, 2012b). The studies by Fedorova-Dahms et al. (2011a, 2011b) and Schmitt et al. (2012a, 2012b) were related to DHA-rich oil described in GRN 553 (DHASCO-B) and GRN 677, respectively. Additionally, GRNs 731 described unpublished acute toxicity study of another source of DHA-rich oil derived from *Schizochytrium* sp. Thus, our comparison has focused on the DHA-rich oils described in these GRAS notices and the FCC standards.

Table 7 presents the specifications of Hubei Fuxing's DHA-rich oil in comparison with those described in GRNs 137 (page 21, stamped page 26), 553 (pages 17-18, stamped pages 23-24), 677 (page 15), and 731 (page 18). The specifications of Hubei Fuxing's DHA-rich oil were also compared with Food Chemicals Codex (FCC) standards, DHA-rich oils derived from

Schizochytrium sp. and from *Crypthecodinium cohnii*. The bioequivalence of two sources of DHA-rich oils was established when administered in a blend with ARA oil to preweaning farm piglets and human infants (Fedorova-Dahms et al., 2014; Yeiser et al., 2016). Thus, it is reasonable to compare specifications and fatty acid profiles of Hubei fuxing's DHA-rich oil with other DHA-rich oils described in these GRAS notices and the Food Chemicals Codex (FCC) standards (FCC, 11th edition, 2018).

Table 8 summarizes the analytical values for Hubei Fuxing's DHA-rich oil. Five non-consecutive lots of DHA-rich oil samples were analyzed for DHA, acid value, peroxide value, free fatty acids, trans fatty acids, heavy metals, and microbiology (in particular, *Salmonella* and *Cronobacter* sp.) to ensure that Hubei Fuxing's DHA-rich oil meets the specifications. The DHA content is comparable to those described in previous GRAS notices derived from *Schizochytrium* sp. sources. The DHA specification for Hubei Fuxing's DHA-rich oil meets FCC specifications for DHA-rich oil: 30-40% DHA for DHA-rich oil derived from *Schizochytrium* sp. and 35-47% DHA for DHA-rich oil derived from *Crypthecodinium cohnii*. The specification for acid value of Hubei Fuxing's DHA-rich oil is set at ≤0.8 mg potassium hydroxide (KOH)/g; this value is slightly higher than those specified in GRN 137 (≤0.5 mg KOH/g) but is lower than a FCC standard (≤1.0 mg KOH/g) established for ARA, another polyunsaturated fatty acid that is commonly used in infant formulas (Food Chemicals codex [FCC], 11th edition, 2018). The FCC has not set a limit for the acid value for DHA-rich oils (FCC, 11th edition, 2018).

Tables 9 and 10 show the fatty acid profile of Hubei Fuxing's DHA-rich oil and its comparison with those described in GRNs 137 (page 24, stamped page 29), 553 (stamped pages 24 -26), 677 (page 20), and 731 (pages 20-21).

The fatty acid profile of Hubei Fuxing's DHA-rich oil is similar to those of other DHA-rich oils described in GRNs 137, 677, and 731; palmitic acid and docosapentaenoic acid (DPA [n-6]) are the predominant fatty acids next to DHA (Tables 9 and 10). It is noteworthy that the fatty acid profile of Hubei Fuxing's DHA-rich oil is substantially equivalent to that described in GRN 677 (Hubei Fuxing vs. GRN 677: mean DHA content, 38.9 vs. 40.2 %; palmitic acid, 26.2 vs. 25.4%; DPA, 8.76 vs. 7.81%; EPA, 0.31 vs. 1.18%). However, oleic acid and palmitic acid are predominant next to DHA in the DHA-rich oil described in GRN 553. The eicosapentaenoic acid (EPA) and DPA (n-6) contents of Hubei Fuxing's DHA-rich oil were lower than the FCC specification for the DHA oil from *Schizochytrium* sp., but higher than those set for the oil derived from *C. cohnii* (EPA: Hubei Fuxing vs. $FCC_{Schizochytrium\ sp.}$ vs. $FCC_{C.\ cohnii}$ = 0.31 vs.1.3-3.9 vs. ≤0.1%; DPA [n-6]: Hubei Fuxing vs. $FCC_{Schizochytrium\ sp.}$ vs. $FCC_{C.\ cohnii}$ = 8.76 vs.10.5-16.5 vs. ≤0.1%). The DPA content of Hubei Fuxing's DHA-rich oil (8.76%) was lower than the values reported in GRN 137 (13.5%) and GRN 731 (10.33%) but higher than that described in GRN 553 (an average of 2.53%). The upper limit for DPA [n-6] set by the FCC is 16.5% for the DHA oil from *Schizochytrium* sp.

Overall, it is concluded that the fatty acid profile of Hubei Fuxing's DHA-rich oil is comparable to those described in the above mentioned GRAS notices, in particular, GRN 677.

Table 7. Specifications of DHA-Rich Oil

Parameter	Specifications							Methods of Analysis for the Current Notice
	Current notice	GRN 137[a]	GRN 553[b]	GRN 677[b]	GRN 731[b]	FCC[c]	FCC[d]	
DHA*, %	≥36[e]	32 – 45[f]	≥35[f]	≥35[f]	>45[e]	30-40[f] ≥30	35-47[f] ≥35	AOCS Ce 2-66; AOCS Ce 1-62; or AOCS Ce 2-66 mod; AOCS Ce 1b-89 mod.
Acid value, mg potassium hydroxide (KOH)/g	≤ 0.8	≤0.5		≤0.5	< 0.5			AOCS Cd 3d-63
Free fatty acid, as % oleic acid	≤ 0.4		≤0.4		< 0.1	≤ 0.4	≤ 0.4	AOCS Cd 3d-63; or AOCS Ca 5a-40
Trans fatty acids, relative area %	≤1.0	≤2.0	≤3.5	≤2.0	<1.0			AOCA Ce 1f-96
Unsaponifiable matter, %	≤3.0	≤4.5	≤3.5	≤3.5	<3.0	≤4.5	≤3.5	AOCS Ca 6b-53
Peroxide value, meq/kg	≤5.0	≤5.0	≤5.0	≤5.0	<5.0	≤5.0	≤5.0	AOCS Cd 8-53
Moisture (direct drying method), wt%	≤0.1	≤0.1	≤ 0.02	≤ 0.05	<0.1			AOCS Ca 2e-84
Docosapentaenoic acid* (DPA, n-6)		10 - 20	≤10					AOCS Ce 2-66; AOCS Ce 1-62; or AOCS Ce 2-66 mod; AOCS Ce 1b-89 mod.
Copper, ppm	≤0.1	≤0.1	≤0.1	<0.1	<0.5			BS EN ISO 17294-2 2016 mod. except Iron - Eurofin internal method ICP-OES
Iron, ppm	≤0.1	≤0.5	≤0.2	<0.2	<0.2			
Lead, ppm	≤0.1	≤0.2	≤0.1	< 0.1	< 0.1	≤0.1	≤0.1	
Arsenic, ppm	≤ 0.1	≤0.5	≤ 0.1	< 0.1	< 0.1	≤ 0.1	≤ 0.1	
Cadmium, ppm	≤0.1		≤ 0.1		< 0.1			
Mercury, ppm	≤0.04	<0.2	≤0.04	< 0.1	< 0.01	≤ 0.1	≤ 0.1	BS EN 13806:2002
Coliforms, cfu/ml	≤10				< 1			AOAC 991.14
Molds, cfu/ml	≤10				< 1			AOAC 997.02
Yeast, cfu/ml	≤10				< 1			
Salmonella/25 ml	ND				ND			AOAC-RI 121501[g]
Cronobacter sp./10 g	ND							ISO 22964:2017

AOAC = Association of Official Analytical Chemists; AOCS = American Oil Chemist's Society; BS-EN = British adoption of a European (EN) standard; CFU = Colony Forming Units; ICP OES = inductively coupled plasma optical emission spectrometer; mod=modifications; MPN = most probable number; NA = not available; meq = milliequivalents; ND = not detected.
*The samples analyzed in 2019 used AOCS Ce 2-66; AOCS Ce 1-62; and a sample analyzed in 2020 was based on AOCS Ce 2-66 mod; AOCS Ce 1b-89 mod.
[a]DHA-rich oil derived from *Schizochytrium* sp. for selected general food applications;
[b]DHA-rich oil derived from *Schizochytrium* sp. for infant formula applications;
[c]FCC specifications for DHA oil derived from *Schizochytrium* sp.;
[d]FCC specifications for DHA oil derived from *Crypthecodinium cohnii*.
[e] wt% (Eurofins' COAs have reported the DHA content in wt%).
[f]relative area%.
[g]AOAC-RI 121501 refers to a kit method for 96 lysis and real-time PCR reactions for the BAC gene of *Salmonella* sp. detection. Eurofins has an AOAC 'Performance tested' certified status (certification no. RI 121501).
http://members.aoac.org/aoac_prod_imis/AOAC_Docs/RI/19PTM/19C_121501EGSSs.pdf.

Table 8. Summary of Analytical Values for Hubei Fuxing's DHA-Rich Oil*

Parameter	Analytical values					
	D18071 101J	D18081 801J	D18111 401J	D18122 601J	D19122 101D	LOQ
DHA, wt%	38.24	38.06	38.78	38.30	40.95	0.02
Acid value, mg KOH/g	0.52	0.34	0.38	0.38	0.14	0.05
Free fatty acid, as % oleic acid	0.26 / 0.18	0.17 / 0.18	0.19 / 0.20	0.19 / 0.14	0.07 / 0.07	0.01
Trans fatty acids, relative area %	0.20	0.12	0.15	<0.01	0.07	0.01
Unsaponifiable matter, %	1.66	1.04	1.58	1.03	1.87	0.05
Peroxide value, meq/kg	<0.1	2.1	<0.1	1.1	1.9	0.1
Moisture, g/100 g	0.02	0.02	0.02	0.01	0.04%	0.01
Protein, g/100 g	<0.1	<0.1	<0.1	<0.1	<0.1	0.1
Ash, g/100 g	0.04	0.03	0.03	0.05	0.020	0.01
Potassium (K), mg/kg					<3	3
Manganese (Mn), mg/kg	<0.1	<0.1	<0.1	<0.1	<0.1	0.1
Sulphur (S), mg/kg					<20	20
Copper (Cu), mg/kg	<0.1	<0.1	<0.1	<0.1	<0.1	0.1
Iron (Fe), mg/100 g	<0.1	<0.1	<0.1	<0.1	<0.3	<0.3
Lead (Pb), mg/kg	<0.05	<0.05	<0.05	<0.05	<0.05	0.05
Arsenic (As), mg/kg	<0.05	<0.05	<0.05	<0.05	<0.05	0.05
Cadmium (Cd), mg/kg	<0.01	<0.01	<0.01	<0.01	<0.01	0.01
Mercury (Hg), mg/kg	<0.005	<0.005	<0.005	<0.005	<0.005	0.005
Coliforms, cfu/ml	<10	<10	<10	<10	<10	NA
Molds, cfu/g	<10	<10	<10	<10	<10	NA
Yeast, cfu/g	<10	<10	<10	<10	<10	NA
Salmonella/25 ml	ND	ND	ND	ND	ND	NA
Cronobacter sp./10 g	ND	ND	ND	ND	ND	NA

*Samples were taken from 5 non-consecutive batches. NA=not available; ND = Not detected; LOQ=limit of quantitation.

Table 9. Fatty Acid Profile of Hubei Fuxing's DHA-Rich Oil

Parameters, wt%	Sample number					Mean
	D1807 1101J	D1808 1801J	D1811 1401J	D1812 2601J	D1912 2101D	
C08:0 Octanoic (Caprylic)	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
C10:0 Decanoic (Capric)	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
C11:0 Undecanoic (Hendecanoic)	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
C12:0 Dodecanoic (Lauric)	0.04	0.13	0.04	0.13	0.04	0.08
C14:0 Tetradecanoic (Myristic)	0.46	2.60	0.46	2.59	0.35	1.29
C14:1 Tetradecenoic (Myristoleic)	0.02	0.50	<0.02	<0.02	<0.02	<0.12
C15:0 Pentadecanoic	0.79	1.29	0.80	1.32	1.04	1.05
C15:1 Pentadecenoic	<0.02	0.02	<0.02	0.02	<0.02	<0.02
C16:0 Hexadecanoic (Palmitic)	22.24	34.56	22.30	34.82	17.10	26.20
C16:1 Hexadecenoic (Palmitoleic)	0.15	0.27	0.13	0.28	0.12	0.19
C16:2 Hexadecadienoic	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
C16:3 Hexadecatrienoic	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
C16:4 Hexadecatetraenoic	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
C17:0 Heptadecanoic (Margaric)	0.97	0.43	0.99	0.44	1.36	0.84
C17:1 Heptadecenoic (Margaroleic)	0.02	<0.02	0.02	<0.02	<0.02	<0.02
C18:0 Octadecanoic (Stearic)	1.23	1.00	1.25	1.02	1.09	1.12
C18:1 Octadecenoic (Oleic + isomers)	3.25	0.44	3.29	0.44	1.71	1.83
C18:2 Octadecadienoic (Linoleic + isomers)	6.84	0.85	6.99	0.84	4.09	3.92
C18:2 Octadecadienoic Omega 6 (Linoleic)	6.82	0.77	6.88	0.78	4.01	3.85
C18:3 Octadecatrienoic (Linolenic + isomers)	0.84	0.19	0.91	0.19	0.83	0.59
C18:3 Octadecatrienoic Omega 3 (Alpha Linolenic)	0.75	0.13	0.76	0.13	0.62	0.48
C18:3 Octadecatrienoic Omega 6 (Gamma Linolenic)	0.10	0.07	0.15	0.06	0.21	0.12
C18:4 Octadecatetraenoic Omega 3 (Stearidonic)	0.10	0.15	0.11	0.16	0.13	0.13
C20:0 Eicosanoic (Arachidic)	0.26	0.13	0.27	0.13	0.22	0.20
C20:1 Eicosenoic (Gondoic + isomers)	0.03	<0.02	0.06	<0.02	0.04	<0.03
C20:2 Eicosadienoic Omega 6	0.03	<0.02	0.04	<0.02	0.03	<0.03
C20:3 Eicosatrienoic	0.22	0.15	0.23	0.11	0.30	0.20
C20:3 Eicosatrienoic Omega 3	<0.02	0.06	<0.02	<0.02	<0.02	<0.03

C20:3 Eicosatrienoic Omega 6	0.22	0.10	0.23	0.10	0.29	0.19
C20:4 Eicosatetraenoic (Arachidonic + isomers)	0.90	2.20	1.09	2.24	1.17	1.52
C20:4 Eicosatetraenoic Omega 3	0.49	0.48	0.50	0.50	0.60	0.51
C20:4 Eicosatetraenoic Omega 6 (Arachidonic)	0.41	1.72	0.59	1.74	0.57	1.01
C20:5 Eicosapentaenoic Omega 3	0.19	0.40	0.23	0.46	0.26	0.31
C21:5 Heneicosapentaenoic Omega 3	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
C22:0 Docosanoic (Behenic)	0.15	0.08	0.16	0.08	0.14	0.12
C22:1 Docosenoic (Erucic + isomers)	<0.02	<0.02	<0.02	0.04	<0.02	<0.02
C22:2 Docosadienoic Omega 6	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
C22:3 Docosatrienoic, Omega 3	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
C22:4 Docosatetraenoic Omega 6	0.05	0.03	0.06	0.03	0.07	0.05
C22:5 Docosapentaenoic	10.62	4.92	10.96	5.10	12.61	8.84
C22:5 Docosapentaenoic Omega 3 (DPA [n-3])	0.05	0.09	0.06	0.11	0.11	0.08
C22:5 Docosapentaenoic Omega 6 (DPA [n-6])	10.58	4.83	10.90	4.99	12.50	8.76
C22:6 Docosahexaenoic Omega 3	**38.24**	**38.06**	**38.78**	**38.30**	**40.95**	**38.87**
C24:0 Tetracosanoic (Lignoceric)	<0.02	<0.02	0.15	0.06	<0.02	<0.054
C24:1 Tetracosenoic (Nervonic)	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
Total Fat as Triglycerides	91.43	92.31	93.15	92.76	87.19	91.37
Total Fatty Acids Calc.	87.69	88.42	89.35	88.85	83.68	87.60

LOQ: individual fatty acids = 0.02 wt%, total fat as triglycerides = 0.1 wt%.

Table 10. Comparison of Fatty Acid Profiles of DHA-Rich Oils, wt% unless noted otherwise

	Current notice	GRN 137[a]	GRN 553[b,*]	GRN 677[b,*]	GRN 731[b]	FCC[c,*]	FCC[d,*]
DHA (Docosahexaenoic acid) specifications	≥36	32 - 45	≥35	≥35	>45	35-40; ≥30	35-47; ≥35
Actual content, %	38.87	35.0	43.3	40.22	50.7		
Fatty Acid Profile, g/100g							
C 6:0 (Caproic acid)					< 0.02		
C 8:0 (Caprylic acid)	<0.02				< 0.02		
C 10:0 (Capric acid)	<0.02				< 0.02		
C 12:0 (Lauric acid)	0.08	0.4	<0.10	0.91	0.10		
C 14:0 (Myristic acid)	1.29	10.11	1.18	11.87	0.82		
C 14:1 (Myristoleic acid)	<0.12		<0.10	<0.10	< 0.02		
C 15:0 (Pentadecanoic acid)	1.05		0.24	0.52	0.06		
C 15:1 (Pentadecenoic acid)	<0.02				0.07		
C 16:0 (Palmitic acid)	26.20	23.68	13.78	25.43	20.96		
C 16:1 (Palmitoleic acid)	0.19	1.76	<0.10	3.42	0.51		
C 17:0 (Margaric acid or Heptadecanoic acid)	0.84		<0.10	<0.12	0.08		
C 18:0 (Stearic acid)	1.12	0.45	1.65	0.82	1.30		
C 18:1 (Oleic acid)	1.83	NA		4.77	0.27		
C 18:1n7 (Vaccenic acid)		Trace-1.36	0.26		0.51		
C 18:2n6 (Linoleic acid)	3.85		2.01	<0.33	< 0.02	NA	0-1.0
C 18:3n3 (alpha-Linolenic acid)	0.48		<0.10	NA	0.14		
C 18:3n6 (gamma-Linolenic acid)	0.12		NA	0.23	0.09		
C 20:0 (Arachidic acid)	0.20		0.32	<0.10	0.29		
C 20:1 (Eicosenoic acid)	<0.03			<0.06	< 0.02		
C 20:2n6 (Eicosodienoic acid)	<0.03		0.13		< 0.02		
C 20:3n3 (Eicosatrienoic acid)	<0.03		<0.1		1.34		
C 20:3n6 (homo-gamma-Linolenic acid)	0.19		<0.1	<0.11	0.21	1.7-2.8	0-0.1
C 20:4n6 (Arachidonic acid)	1.01	0.94	0.69	0.70	0.15	0.6-1.3	
C 20:5n3 (Eicosapentaenoic acid; EPA)	0.31	2.63	6.23	1.18	0.70	1.3-3.9	0-0.1

C 21:0 (Heneicosanoic acid)					0.04		
C 22:0 (Behenic acid)	0.12			<0.10	0.15		
C 22:1n9 (Erucic acid)					< 0.02		
C 22:2n6 (Docosadienoic acid)	<0.02		0.53		< 0.02		
C 22-5n3 (Docosapentaenoic acid)	0.08		0.76		0.11		
C 22-5n6 (Docosapentaenoic acid)	8.76	13.5	2.53	7.81	10.33	10.5-16.5	0-0.1
C 23:0 (Tricosanoic acid)					< 0.02		
C 24:0 (Lignoceric acid)	<0.054			<0.10	0.15		
C 24:1 (Nervonic acid)	<0.02				0.41		

NA= not available; [a]DHA-rich oil derived from *Schizochytrium* sp. for selected general food application; [b]DHA-rich oil derived from *Schizochytrium* sp. for infant formula application; [c]FCC specifications for DHA oil derived from *Schizochytrium* sp.; [d]FCC specifications for DHA oil derived from *Crypthecodinium cohnii*.

*Fatty acid contents were reported as relative area%.

Table 11 summarizes the sterol content in Hubei Fuxing's DHA-rich oil. Table 12 presents the sterol content of Hubei Fuxing's DHA-rich oil in comparison with those described in GRN 553 (pages 21-22, stamped pages 27-28) and 677 (page 21). Table 12 summarizes the total concentrations of plant sterols and plant stanols (0.31 wt% in fat) in Hubei Fuxing's DHA-rich oil. This level is comparable to the average total sterol values calculated from the values reported in GRN 553 (0.54 wt%) and GRN 677 (0.15 wt%).

Table 11. Plant Sterols and Plant Stanols in Hubei Fuxing's DHA-Rich Oil

Parameters, wt%	Lot number					Mean,
	D1807 1101J	D1808 1801J	D1811 1401J	D1812 2601J	D1912 2101D	
Brassicasterol	0.0150	0.0090	0.0150	0.0100	0.0150	0.0128
Cholesterol	0.2100	0.1130	0.2100	0.1140	0.2790	0.1852
Campesterol	0.0150	0.0050	0.0150	0.0050	0.0080	0.0096
Campestanol	0.0010	0.0010	0.0010	0.0010	0.0070	0.0022
Stigmasterol	0.0270	0.0100	0.0280	0.0100	0.0380	0.0226
Sitosterol	0.0670	0.0230	0.0680	0.0230	0.0790	0.0520
Sitosterol + delta-5-avenasterol	0.0070	0.0050	0.0080	0.0060	0.0100	0.0072
Delta-5,24-stigmastadienol	0.0100	0.0040	0.0100	0.0030	0.0110	0.0076
Delta-7-stigmastenol	0.0280	0.0130	0.0280	0.0130	0.0240	0.0212
delta-7-Avenasterol	0.0060	0.0010	0.0060	0.0010	0.0120	0.0052
Cycloartenol	0.0020	0.0020	0.0030	0.0020	ND	0.00225
24-Methylenecycloartanol	0.0020	0.0030	0.0030	0.0030	0.0030	0.0028
Citrostadienol	0.0020	0.0010	0.0020	0.0010	ND	0.0015
Total plant sterols + plant stanols	0.3720	0.1860	0.3750	0.1880	0.4400	0.3122*
Unidentified sterols	0.196	0.115	0.197	0.116	0.237	0.1722

The data were provided by Eurofins. *The calculated sum of individual values was 0.3322 wt%. The mean value (0.3122 wt%) reported in the table is based on Eurofins' analytical values for total plant sterols and plant stanols (method of analysis - NMKL 198:2014).

Table 12. Comparison of Plant Sterols in DHA-Rich Oils

Parameters, wt%	Current Notice	GRN 553*	GRN 677*
Brassicasterol	0.0128	0.0070	<0.0045
Cholesterol	0.1852	0.0664	0.0345
Campesterol	0.0096	0.0097	0.0035
Campestanol	0.0022	0.0005	<0.0002
Stigmasterol	0.0226	0.3413	<0.0204
Unidentified sterols	0.1722		
Sitosterol	0.0520	0.0610	0.0186
Sitostanol + delta-5-avenasterol	0.0072		
Delta-5,24-stigmastadienol	0.0076	0.0022	0.0086
Delta-7-stigmastenol	0.0212	0.0103	<0.0129
delta-7-Avenasterol	0.0052	0.0049	0.0065

Cycloartenol	0.00225		
24-Methylenecycloartanol	0.0028		
Citrostadienol	0.0015		
Others*		0.0356	0.0413
Total plant sterols + plant stanols	0.3122	0.54*	0.15*

* The values represent total sterols in fats (wt%). Like other DHA-rich oil (GRN 677), it is assumed that Hubei Fuxing's DHA oil is composed of 99-100% fats. It is noteworthy that GRNs 553 and 677 reported fatty acid values as %area without reporting the absolute quantity. On the other hand, the current notice reports quantitative values of individual fatty acids which may not capture all fatty acids.

2.D. Stability

The stability of Hubei Fuxing's DHA-rich oil is expected to be similar to those of other algal oils with a similar DHA content. DHA algal oil is typically shipped and stored in a tightly closed, nitrogen-blanketed, light-resistant container under frozen conditions (-25°C). As discussed in GRN 677, the results of one study support the stability of the frozen product for a period of 1 year. Hubei Fuxing recommends the product be used (best before date) within 1 year from the date of manufacture.

2.E. Intended Technical Effects

DHA-rich oil will be used as a food ingredient in selected conventional foods and in term and preterm infant formulas.

PART 3. EXPOSURE ESTIMATES

3.A. Exposure Estimates

Selected General Foods

In accordance with 21 CFR §184.1(b)(2), the ingredient may be used in food to ensure that the total intake of EPA or DHA does not exceed 3.0 grams/person/day (FDA, 2005). DHA-rich oil will be added to the same food categories, excluding egg, meat, poultry, and fish products, as those currently listed in 21 CFR 184.1472(a)(3) (menhaden oil) and GRN 137 at maximum use levels that are 27.78% of those specified in that regulation. As discussed in GRN 137, the proposed use levels of the DHA-rich oil are expected to result in a maximum dietary exposure of less than 1.5 g of DHA per day. Because DHA-rich oil is intended to be used as an alternative to menhaden oil, there will be no increase in exposure to DHA from the intended use described in Table 1. Hubei Fuxing's DHA-rich oil is not to be combined with any other added oil that is a significant source of DHA or EPA. It would be possible, however, to blend DHA-rich oil with other sources of DHA and/or EPA.

The 27.78% value was derived from the following factors:

1) Since menhaden oil is considered GRAS at a level providing no more than 3 grams of DHA and EPA per day, the use levels in each food category are decreased by 50% so that the total daily consumption of DHA from the DHA-rich oil will be no more than 1.5 grams per day.
2) The levels of use are based on the quantity of DHA-algal oil that can be added to each product. Additional adjustment is needed because the DHA-algal oil has a different concentration of DHA than that found in menhaden oil. DHA-algal oil contains approximately 36 wt% compared to about 20% of combined EPA and DHA in menhaden oil. An additional adjustment of 55.56% (20/36) is needed to accommodate the different concentrations of DHA in the two oils.
3) The 27.78% adjustment is calculated by multiplying the 50% adjustment that is needed in accordance with the first bullet point above by the 55.56% adjustment that is needed in accordance with the second bullet point above, i.e., (0.50) x (0.5556) x 100 = 27.78%.

These are the same food categories (except egg, meat, poultry, and fish products) found in the GRAS notification for DHA-algal oils (GRN 137, stamped pages 10 to 12 and 27 to 28 - FDA, 2004; GRN 732, page 25 - FDA, 2018b) for which the agency did not raise any objections to the company's conclusion that DHA-algal oils derived from *Schizochytrium* sp. would be considered GRAS when used in the food categories identified for menhaden oil.

The EDIs of DHA established in the early 2000s when the menhaden oil rule was finalized (FDA, 2005) and when DHA-rich oil derived from *Schizochytrium* sp. (GRN 137 - FDA, 2004) received no question letters from the FDA are still applicable. Our comparative National Health and Nutrition Examination Survey (NHANES) analysis (2001-2002 vs. 2015-2016) revealed that the total number of food servings consumed was slightly decreased in the mid-2010s when compared to the early 2000s. For example, the mean and 90th percentile

numbers of total food servings of the 26 food categories specified in Table 1 were 11.8 and 20.0 servings, respectively, in 2001-2002 and 11.0 and 18.9 servings, respectively, in 2015-2016 for all American population aged 1-99 years (detailed analytical data not shown).

Infant Formulas

Hubei Fuxing's DHA-rich oil may be used at a maximum use level of 1.39% of total dietary fat because it has ≥36% DHA. This level corresponds to a maximum of 0.5% of total dietary fat as DHA. Because the DHA will be used at a maximum use level of 0.5% of total fatty acids (i.e., a maximum of 0.5% total fat as DHA), the intended use will result in 27 to 33 mg DHA/kg bw/day (or 75 - 93 mg DHA-rich oil/kg bw/day). This estimated DHA intake is consistent with current DHA recommendations for preterm and term infants of 18 to 60 mg/kg bw/day depending on gestational age (Koletzko et al., 2014).

The 75 to 93 mg DHA-rich oil/kg bw/day values were derived by the following factors:

1) Assuming human infants consume about 100 to 120 kcal/kg bw/day, of which fat comprises about 50%, an infant will consume about 50 - 60 kcal/kg bw/day of fat,
2) These levels correspond to about 5.555 - 6.67 g of fat/kg bw/day (1 g fat=9 kcal), and
3) The DHA-rich oil intake of 1.39% of daily fat for an infant would correspond to about 77 - 93 mg DHA-rich oil/kg bw/day (5,555 mg/kg bw/day x 0.01389 = 77.2 mg/kg bw/day; 6,670 mg/kg bw/day x 0.01389 = 92.6 mg/kg bw/day).

An alternative means of calculation is simply based of the DHA content in the DHA-rich oil; 27- 33 mg DHA/kg bw/day corresponds to 75 to 92 mg DHA-rich oil/kg bw/day since DHA-rich oil contains ≥36% DHA (27 mg/kg bw/day/0.36 = 75 mg/kg bw/day; 33 mg/kg bw/day/0.36 = 91.7 mg/kg bw/day).

Hubei Fuxing's DHA-rich oil is intended for use in infant formula in a similar manner as the currently approved oils. Hubei Fuxing's DHA-rich oil is expected to be used as an alternative to existing DHA-rich oils. Thus, cumulative EDIs are not expected to be changed.

3.B. Food Sources of DHA

Human milk provides small quantities of DHA and ARA, usually less than 1% of total fatty acids (Brenna et al., 2007). Fish oil and egg yolks also are known to be excellent sources of DHA.

Summary of Exposure Estimates

For general food applications, DHA-rich oil will be added to the same food categories as those currently listed in 21 CFR 184.1472(a)(3) (menhaden oil) at the maximum use levels, with the exception of egg, meat, poultry, and fish products. The proposed use levels of the DHA-rich oil are expected to result in a maximum dietary exposure of 1.5 g of DHA per day. To ensure the safe use of the substance, DHA-rich oil is intended to be the sole source of DHA in any given food category.

For infant formulas, the intended use will result in 27 - 33 mg DHA/kg bw/day (or 75 - 93 mg DHA-rich oil/kg bw/day), which is consistent with current DHA recommendations for term and preterm infants of 18 - 60 mg/kg bw/day depending on the gestational age.

PART 4. SELF-LIMITING USE LEVELS

No known self-limiting levels of use are associated with the DHA-rich oil.

PART 5. HISTORY OF CONSUMPTION

EXPERIENCE BASED ON COMMON USE IN FOODS BEFORE 1958

The statutory basis for the conclusion of GRAS status of algal DHA-rich oil in this document is not based on common use in food before 1958. The GRAS determination is based on scientific procedures.

PART 6. NARRATIVE

6.A. Current Regulatory Status

Numerous algal and marine sources of DHA have been evaluated by the FDA and other global regulatory agencies over the past 18 years for the proposed incorporation in food for human consumption. The FDA previously reviewed the safety of fish oil containing two omega-3 fatty acids, EPA and DHA, in the 1997 final rule affirming menhaden oil as GRAS (FDA, 1997). The FDA raised concerns about the consumption of high levels of EPA and DHA, which may increase bleeding time, increase levels of low-density lipoproteins cholesterol (LDL-C), and have an effect on glycemic control in subjects with type 2 diabetes (menhaden oil final rule; 62 FR 30751; June 5, 1997). Based on this review, the FDA concluded that a combined intake of EPA and DHA of up to 3 g/person/day would not result in any adverse health effects (FDA, 1997). In 2005, FDA issued a final rule on menhaden oil, reallocating the use levels and categories of use within the GRAS affirmation, but ensuring daily intakes of EPA and DHA do not exceed 3 g/person/day (FDA, 2005). Because DHA represents approximately one half of the combined DHA plus EPA, it is reasonable to consider that the acceptable daily intake (ADI) of DHA is 1.5 g/person/day. Subsequently, GRAS notices on DHA-rich oil derived from *Schizochytrium* sp. (GRN 137 - FDA, 2004; GRN 732 - FDA, 2018b) received no question letters by the FDA.

As shown in Table 13, algal DHA-rich oil derived from *Schizochytrium* sp. received GRAS notice status with U.S. FDA for infant formula applications (GRN 553 -FDA, 2015; GRN 677 - FDA, 2017; GRN 731 - FDA, 2018a, and GRNs 776/777 - FDA, 2018c, 2018d) and selected conventional food applications (GRN 137- FDA, 2004; GRN 732 - FDA, 2018b; GRN 836 -FDA 2019a; GRN 843/844 – FDA, 2019b, 2019c).

Table 13. Regulatory Approvals for Use of DHA-Rich Oil Derived from *Schizochytrium* sp. in Foods and Infant Formulas

Item	Year Approved	Submission
Foods with intended uses as a direct food ingredient in the same categories as considered GRAS for menhaden oil [21CFR184.1472(a)(3)]		
GRN 137	2004	Algal DHA (32-45%) derived from *Schizochytrium* sp.
GRN 732	2018	Algal oil (>45% DHA) derived from *Schizochytrium* sp. (except fish products)
Foods with intended uses in selected conventional foods		
GRN 836	2019	Algal oil (50-60% DHA) derived from *Schizochytrium* sp.
GRN 843	2019	Algal oil (≥35% DHA) derived from *Schizochytrium* sp.
GRN 844	2019	Algal oil (≥55% DHA) derived from *Schizochytrium* sp.
Infant Formula		
GRN 553	2015	Algal oil (≥35% DHA) derived from *Schizochytrium* sp.
GRN 677	2017	Algal oil (≥35% DHA) derived from *Schizochytrium* sp.
GRN 731	2018	Algal oil (>45% DHA) derived from *Schizochytrium* sp.
GRN 776	2018	Algal oil (≥35% DHA) derived from *Schizochytrium* sp.

GRN 777	2018	Algal oil (≥55% DHA) derived from *Schizochytrium* sp.

6.B. Review of Safety Data

As the DHA-rich oil in this GRAS notice has similar specifications compared to those described in the previous FDA GRAS notices involving algal DHA-rich oils (Table 7), it is recognized that the information and data in those GRAS notices are pertinent to the safety evaluation of the DHA-rich oil in this GRAS notice. Based on a comparison of the specifications and the composition for these products, it is concluded that they are essentially similar. In particular, the fatty acid profile of Hubei Fuxing's DHA-rich oil is substantially equivalent to that of DHA-rich oil ONC-T18 whose safety was evaluated in the studies by Schmidt et al. (2012a – page 3568, 2012b – page 4150) (Hubei Fuxing vs. ONC-T18: DHA content, 38.9 vs. 40.2 %; palmitic acid, 26.2 vs. 26.6%; DPA, 8.76 vs. 7.9%; EPA, 0.31 vs. 0.87%). Thus, it is reasonable to expect that the data reported in Schmidt et al. (2012a, 2012b) are pertinent to the safety evaluation of Hubei Fuxing's DHA-rich oil.

The safety of DHA-rich oils derived from *Schizochytrium* sp. was evaluated in animals toxicity studies, and/or mutagenicity/genotoxicity studies by many research groups and the data are presented in the published papers (Falk et al., 2017; Fedorova-Dahms et al., 2011a, 2011b; Lewis et al., 2016; Schmitt et al., 2012a, 2012b) and previous GRAS notices. Therefore, this notice incorporates by reference the safety and metabolic studies discussed in those GRAS notices and will not discuss previously reviewed references in detail. Additionally, this notice discusses human studies that have been published between June 2017 and December 2019.

6.B.1. Metabolic Fate of DHA (adopted from Kremmyda et al., 2011; Kroes et al., 2003; Martin et al., 1993)

DHA is mainly found in the form of triglycerides (TGs), although they also occur in phospholipids in breast milk (Martin et al., 1993). In general, dietary TGs undergo enzymatic hydrolysis in the upper intestine to free fatty acids and 2-monoglycerides. These products are then integrated into bile acid micelles for diffusion into the interior of the intestinal epithelial cells for subsequent incorporation into new or reconstituted TGs (Kroes et al., 2003). These reconstructed TGs enter the lymph in the form of chylomicrons for transport to the blood, which allows distribution and incorporation into plasma lipids, erythrocyte membranes, platelets, and adipose tissue. The chylomicron-containing TGs are hydrolyzed by lipoprotein lipase during the passage through the capillaries of adipose tissue and the liver to release free fatty acids to the tissues for metabolism or for cellular uptake, with subsequent re-esterification into TGs and phospholipids for storage as energy or as structural components of cell membranes. The metabolism of fatty acids occurs in the mitochondria following their transport across the mitochondrial membrane in the form of acylcarnitine.

Fatty acids are metabolized predominantly via beta-oxidation, a process that involves shortening of the fatty acid carbon chain and the production of acetic acid and acetyl CoA, which combines with oxaloacetic acid and enters the citric acid cycle for energy production. The degree

of transport of fatty acids across the mitochondrial membrane is contingent upon the length of the carbon chain; fatty acids of 20 carbons or more are transported into the mitochondria to a lesser degree than shorter chain fatty acids. Therefore, long chain fatty acids, such as DHA, may not undergo mitochondrial beta-oxidation to the same extent (Kroes et al., 2003). Instead, they are preferentially channeled into the phospholipid pool where they are rapidly incorporated into the cell membranes of the developing brain and retina. These fatty acids may be conditionally essential depending on the essential fatty acid availability.

Bioequivalence of two types of algal DHA-rich oils

Numerous GRAS notices have considered that DHA from algal sources is equivalent to that of fish oil. In addition, the bioequivalence of two types of algal DHA-rich oils (derived from either *Crypthecodinium cohnii* [DHASCO®] or *Schizochytrium* sp. [DHASCO-B®]) was demonstrated in preweaning farm piglets and in humans when administered in a blend with ARA oil (Fedorova-Dahms et al., 2014; Yeiser et al., 2016).

In the study by Fedorova-Dahms et al. (2014), blends of DHA- and ARA-rich oils were tested for both types of DHA-rich algal oils; a lower dose provided 0.32% and 0.64% of total fatty acids as DHA and ARA, respectively and a higher dose provided 0.96% and 1.92% of total fatty acids as DHA and ARA, respectively. The high doses of DHA correspond to 283.9 and 305.4 mg/kg bw/day for males and females, respectively, in the DHASCO-B® groups and 288.4 and 294.4 mg/kg bw/day, respectively, in the DHASCO® group. There were no treatment-related effects of DHA/ARA on piglet growth and development, hematology, clinical chemistry, urinalysis, and terminal necropsy parameters. No differences were observed in the DHA concentrations in plasma, red blood cell (RBC), heart, liver, and brain, but showed dose-related accumulation. The authors concluded that the dietary exposure to the two types of DHA-rich algal oils was well tolerated by the neonatal piglets during the 3-week dosing period right after birth, and both DHA-rich algal oils were bioequivalent.

In addition, the study by Yeiser et al. (2016) demonstrated that DHASCO® (derived from *C. cohnii*) and DHASCO-B® (derived from *Schizochytrium* sp.) were equivalent sources of DHA as measured by circulating RBC DHA in infants. Healthy term infants were randomized to receive one of the study formulas (17 mg DHA/100 kcal), either DHASCO® (n=140) or DHASCO-B® (n=127) from 14 to 120 days of age. Study formulas were provided as ready-to-use liquids (20 cal/fluid ounce) with ARA (34 mg/100 kcal) and a prebiotic blend of polydextrose and galactooligosaccharide (GOS) at 4 g/L (1:1 ratio). Compared to the control formula (DHASCO®), the 90% confidence interval for the group mean (geometric) total RBC DHA ratio for the DHASCO-B® group was 91-104%. These values fell within the pre-specified equivalence limit of 80 to 125%. In addition, no significant group differences were noted in growth rates, RBC concentrations of total or individual saturated and monounsaturated fatty acid concentrations, and tolerance. This study demonstrated that both types of DHA-rich oils were safe, well-tolerated, and associated with normal growth. The results from this study indicate that both types of algal DHA-rich oils are bioequivalent when circulating RBC DHA is used as a

biomarker. The results from these studies indicate that the data obtained from studies of the two types of DHA-oils can be interchangeable.

6.B.2. Studies on Mutagenicity and Genotoxicity of DHA-Rich Oil Derived from *Schizochytrium* sp.

Due to the abundance of literature, the review of mutagenicity and genotoxicity studies has focused on studies of DHA-rich oil derived from *Schizochytrium* sp. instead of DHA-rich oil from various sources.

Bacterial Reverse Mutation Assays for Hubei Fuxing's DHA-Rich Oil (Gao, 2019a)

In the reverse mutation assay using five strains of *Salmonella typhimurium* (TA97, TA98, TA100, TA102, and TA1535), Hubei Fuxing's DHA-rich oil (100, 50, 15, and 12.5 µL/plate, respectively) did not increase the number of revertant colonies in any tester strain in the presence or absence of metabolic activation by S9 mix. None of the revertant colonies exceeded three times the mean of the solvent control in the presence or absence of the metabolic activation when treated with the DHA-rich oil. There was no dose-related increase over the range tested for any of the five tester strains used. The data indicated that Hubei Fuxing's DHA-rich oil was non-mutagenic under the test conditions. Details are described in Appendix C. This information is unpublished. It is included to ensure a comprehensive review of existing evidence but is not considered key evidence in the evaluation of GRAS status.

Studies of Other Sources of DHA-Rich Oil Reviewed in Previous GRAS Notices

In GRNs 553 (pages 29-33, stamped pages 35-39), 677 (pages 35, 39-41), and 731 (pages 28-30), it was summarized that no studies found mutagenicity or genotoxicity of DHA-rich oil or DHA-rich microalgae (DRM) from *Schizochytrium* sp. The studies reviewed in these GRAS notices include bacterial reverse mutation assays (Hammond et al., 2002; Fedorova-Dahms et al., 2011a, 2011b; Lewis et al., 2016; Schmitt et al., 2012a), chromosome aberration assays (Fedorova-Dahms et al., 2011a, 2011b; Hammond et al., 2002; Lewis et al. 2016; Schmitt et al., 2012a), *in vivo* micronucleus tests in mice and rats (Fedorova-Dahms et al., 2011a, 2011b; Hammond et al., 2002; Lewis et al., 2016; Schmitt et al., 2012b), mammalian erythrocyte micronucleus tests (Lewis et al., 2016), and *in vitro* CHO AS52/XPRT gene mutation assay (Hammond et al., 2002), and did not show any mutagenicity or genotoxicity of DHA-rich algal oil and DRM under the test conditions. Overall, studies consistently show that all preparations of DHA-rich oil are not mutagenic or genotoxic.

6.B.3. Animal Toxicity Studies of DHA-Rich Oil and DHA-Rich Microalgae (DRM) Derived from *Schizochytrium* sp.

Due to the abundance of literature, the review of animal toxicity studies has focused on studies of DHA-rich oil derived from *Schizochytrium* sp. instead of DHA-rich oil from various sources. The results of various animal toxicity studies are summarized in Table 14.

Acute Toxicity Study of Hubei Fuxing's DHA-Rich Oil

Gao (2019b) evaluated the acute toxicity of DHA-rich oil after oral administration in rats. The test substance was administered to young rats by gavage at doses of 0 (control), 0.91, 1.82, or 3.64 g/kg body weight (bw) (or 0, 1.0, 2.0, or 4.0 mL/kg bw; 5 males and 5 females per group). Animals were observed for 14 days to monitor changes in clinical signs (i.e., changes in eyes, mucous membranes, or behavior patterns; loss of fur or scabbing), body weight, and clinical signs, as well as food consumption. No animal died during the 14-day observation period, and no clinical signs of abnormality were found among the groups. No treatment-related abnormalities were observed in the macroscopic examinations. In summary, the acute oral LD_{50} for DHA-rich oil was determined to be above 3.64 g/kg bw (or 4.0 mL/kg bw, the maximum dose volume) in both male and female rats. Details are described in Appendix D. This information is unpublished. It is included to ensure a comprehensive review of existing evidence but is not considered key evidence in the evaluation of GRAS status.

Studies of Other DHA-Rich Oils from *Schizochytrium* sp.

The No Observed Adverse Effect Levels (NOAELs) of other sources of DHA-rich oils and DHA-rich microalgae (DRM) are summarized as follows:

1) For DHA-rich oils, the NOAELs, established from subchronic toxicity studies, ranged from 3,149 to 5,000 mg/kg bw/day in rats (Fedorova-Dahms et al., 2011a; Lewis et al., 2016; Schmitt et al., 2012a). The LD_{50} was determined to be over 5 g/kg bw, the highest dose tested, in rats (Schmitt et al., 2012a).

2) From reproductive and developmental toxicity studies of DHA-rich oils, the NOAELs for F_0 were found to range from 2,000 (Schmitt et al., 2012b) to 8,322 mg/kg bw/day (F_0 females during lactation) in rats (Fedorova-Dahms et al., 2011b). In subchronic toxicity studies with an *in utero* phase, the NOAELs for F_1 ranged from 3,526 (males - Schmitt et al., 2012b) to 4,399 mg/kg bw/day (females - Fedorova-Dahms et al., 2011b) in rats.

Studies of DHA-Rich Microalgae from *Schizochytrium* sp.

1) For DHA-rich microalgae (DRM), the NOAEL was found to be 5.746 kg DRM per pig, corresponding to 1.281 kg DHA per pig (DRM contained 22.3% DHA) (Abril et al., 2003). Corresponding amount of DHA-rich oil would be 3.203 kg DHA-rich oil per pig after dividing with a conversion factor of 0.4. The 0.4 value was derived based on the assumption that a typical DHA-rich oil would contain 40% DHA. Thus, to convert the DHA value to DHA-rich oil value, the DHA value is divided by 0.4.

2) In a subchronic toxicity study on another source of DRM, which contains 8.7% DHA on a dry weight basis (page 193), the authors reported NOAEL of 4,000 mg DRM/kg bw/day in rats (Hammond et al., 2001a). The corresponding DHA level was calculated based on the following formula: *x* mg DRM x 0.087 (% DHA on a dry wt. basis) = *y* mg DHA. Thus, corresponding DHA level is 348 mg/kg bw/day (4,000 x 0.087 = 348 mg DHA). Assuming a typical DHA-rich oil contains an average of 40% DHA, the corresponding DHA-rich oil level was obtained by dividing the DHA level by 0.4, which

corresponds to 870 mg/kg bw/day of DHA-rich oil (y mg DHA/0.4= z mg DHA-rich oil or 348 mg/0.4= 870 mg DHA-rich oil).

However, in a reproductive and developmental toxicity study in rabbits by Hammond et al. (2001b), both the high-dose (1,800 mg/kg/day) DRM and fish oil control groups experienced marked and sustained reduction in food consumption during the prenatal period and a slight increase in abortions. In this rabbit study, one female in the fish oil group and two females in the high-dose DRM group aborted on gestational days 23 and 25/26, respectively. The authors suggested that the presence of higher levels of dietary fat may have contributed to food intake reductions, leading to disruption of normal development and/or maintenance of pregnancy and abortions in these groups. Two of the three rabbits that aborted also had lower numbers of implantation sites (one to three per dam), although corpora lutea counts, which have an inverse association with an increased risk of abortion, were within normal limits. No other treatment-related abnormalities were observed in intrauterine growth, survival, or other developmental toxicity parameters at all dose levels. In summary, the NOAELs were determined to be 600 mg/kg bw/day for maternal toxicity and 1,800 mg/kg bw/day, the highest level tested, for developmental toxicity in rabbits. These levels correspond to 130 mg DHA-rich oil/kg bw/day for maternal toxicity and 392 mg DHA-rich oil/kg bw/day for developmental toxicity in rabbits. However, the authors noted that abortions occur spontaneously more frequently in rabbits than in other commonly used laboratory species and that the incidences of abortions in both the high-dose DRM and fish oil control groups fall within historical limits for the laboratory.

It is noteworthy that the same DRM substance was well tolerated with no adverse effects in a reproductive and developmental toxicity study in rats conducted by the same research group (Hammond et al., 2001b). In rats, the NOAEL was estimated to be 22,000 mg DRM/kg bw/day for both maternal and development toxicity. This level corresponds to 1,914 mg DHA /kg bw/day or 4,785 mg DHA-rich oil/kg bw/day, assuming the DHA content in DRM was 8.7% and a typical DHA-rich oil would contain 40% DHA.

In a single generation reproductive toxicity study, the NOAEL was estimated to be 17,847 and 20,669 mg DRM/kg bw/day for males and females, respectively (Hammond et al., 2001c). The authors stated that these levels of DRM intake correspond to an intake of approximately 1,512 and 1,680 mg/kg bw/day for DHA (page 358 of Hammond et al., 2001c), which may correspond to approximately 3,780 and 4,200 mg DHA-rich oil/kg bw/day for males and females, respectively, based on the same assumption that DHA-rich oil would contain 40% DHA.

Conclusion

For the purpose of safety evaluation, the NOAEL of male rats, 3,149 mg/kg bw DHA-rich oil/day, was chosen from a subchronic toxicity in rats.

Table 14. Animal Toxicity Studies of DHA-Rich Oil or DHA-Rich Microalgae from *Schizochytrium* sp.

Study Design	Dose (purity)	Duration	Species	Primary Observations	NOAEL mg/kg bw/d unless noted otherwise	Reference
Acute Toxicity Study of Hubei Fuxing's DHA-rich Oil						
Acute oral toxicity (gavage)	Up to 4 mL/kg bw (or 3.64 g/kg bw)	Single dose; observed for 14 d	Rat	Clinical signs of abnormality	LD_{50}>>>4 mL/kg bw (or 3.6 g/kg bw)	Gao et al., 2019b
DHA-rich Oil Studies Reviewed in Previous GRAS Notices						
Acute oral toxicity (gavage)	5,000 mg/kg (40.23 area% DHA in DHA-rich oil)	Single dose; observed for 14 d	Rat	No treatment-related adverse effects	LD_{50}>5 g/kg	Schmitt et al., 2012a
Subchronic toxicity (gavage)	1,000, 2,500, or 5,000 mg/kg bw/d (41.37% DHA of total FAs in DHA-rich oil)	90 d	Rat	No treatment-related adverse effects	5,000 (M) 5,000 (F)	Lewis et al., 2016
Subchronic toxicity (diet)	0.5, 1.5, or 5 wt% in diet (37% DHA of total FAs in DHA-rich oil)	90 d	Rat	Reduced food consumption in all treatment and fish oil control groups; attributed to high fat content rather than treatment.	3,149 (M) 3,343 (F)	Fedorova-Dahms et al., 2011a
Subchronic toxicity (diet)	1, 2.5, or 5% in diet (40.23 area% in DHA-rich oil)	90 d	Rat	No treatment-related adverse effects	3,305 (M) 3,679 (F)	Schmitt et al., 2012a
Reproductive and develop-	0.5, 1.5, or 5 wt% in diet	F_0: M & F-28 d premating and	Rat	No treatment-related adverse effects	F_0 premating: 3,466 (M), 4,013 (F);	Fedorova-Dahms et al.,

mental toxicity	(43% DHA of total FAs in DHA-rich oil)	≤14 d mating periods; F-followed by gestation and lactation period; F_1: 90 d with an *in utero* phase, followed by a 4 wk recovery phase			F_0 gestation: 3,469 (F); F_0 lactation: 8,322 (F). F_1 90 day with *in utero* exposure phase: 4,122 (M), 4,399 (F)	2011b
Prenatal develop-mental toxicity (gavage)	400, 1,000, or 2,000 mg/kg bw/d (~42% DHA in DHA-rich oil)	Gestation days 6 to 19	Rat	No treatment-related adverse effects	2,000 for both maternal and embryo/fetal development toxicity	Schmitt et al., 2012b
Reproductive and develop-mental toxicity	0.5, 1.0, 2.5, or 5% in diet (42% DHA in DHA-rich oil)	F_0 M - 89-91 d; F_0 F - 75-77 d	Rat	No treatment-related adverse effects	F_0: 5% (both M and F) in diet; F_0 during premating, 3,421 (M), 3,558 (F); after mating, 2,339 (M); F_0 during gestation, 3,117 (F); F_0 during lactation, 7,464 (F)	Schmitt et al., 2012b
		F_1 M- 106-107 d with an *in utero* phase; F_1 F -110-111 d with an *in utero* phase	Rat	Developmental toxicity-5% in diet for both M and F. Systematic toxicity-No treatment-related adverse effects in the 5% group males; Higher food consumption, body weight, and body	F_1: 5% in diet (both M and F); F_1: 3,526 (M), 4,138 (F); Systematic toxicity- 5% (M) and 2.5% (F) in diet	

				weight gain in the 5% F_1 female group		
Maternal/ paternal reproductive and develop-mental toxicity (oral gavage)	1,000, 2,500, or 5,000 mg/kg bw/d (41.37% DHA of total FAs in DHA-oil)	M - 98 d (84 d premating + 14 d mating; F - 71 d (14 d premating + 14 d mating+ 22 d pregnancy + 21 d lactation)	Rat	No treatment-related adverse effects	5,000 for maternal toxicity and embryo/fetal development; 5,000 for paternal or maternal treatment-related reproductive toxicity	Falk et al., 2017
DRM Studies Reviewed in Previous GRAS Notices						
Subchronic toxicity (diet)	2.680, 1.169, 3.391, or 5.746 kg DRM per pig (22.3% DHA on a dry wt basis)	2.680 kg DRM/pig-120 d, a whole-life exposure; 1.169, 3.391, or 5.746 kg DRM/pig during the last 42 d	Pig (M)	No treatment-related adverse effects (598, 261, 756, and 1,281 g DHA per pig during expt. period)	5.746 kg DRM/pig (corresponding to 3.203 kg DHA-rich oil/pig*) (M)	Abril et al., 2003
Subchronic toxicity (diet)	400, 1,500, or 4,000 mg/kg bw/d (8.7% DHA on an as-is basis)	13 wk	Rat	No treatment-related adverse effects	4,000 DRM (corresponding to 870 DHA-rich oil*)	Hammond et al., 2001a
Reproduc-tive and develop-mental toxicity (diet)	0.6, 6.0, or 30% DRM in diet (8.7% DHA on a dry wt. basis)	Gestation days 6 to15	Rat	No treatment-related adverse effects	Both maternal and developmental toxicity - 22,000 DRM (corresponding to 4,785 DHA-rich oil*)	Hammond et al., 2001b
Single-generation reproduction		M-15 wk; F-2 weeks prior to mating, during	Rat	No treatment-related adverse effects	17,847 DRM (corresponding to 1,512 DHA or 3,780 DHA-	Hammond et al., 2001c

toxicity (diet)		mating, and throughout gestation and lactation (10 wk)			rich oil*) (M); 20,669 DRM (corresponding to 1,680 DHA or 4,200 DHA-rich oil*) (F)	
Reproductive and develop-mental toxicity (gavage)	180, 600, or 1,800 mg DRM/kg/d (8.7% DHA on a dry wt basis)	F_0 mother-13 d (gestation days 6 to 18)	Rabbit	High-dose (1,800) DHA oil and fish oil groups: F_0 mothers had reduced food consumption and body weight and a slightly higher abortion rate (but within the historical limits for the laboratory)	F_0: 600 DRM (corresponding to 130 DHA-rich oil*) (F); F_1: Developmental, 1,800 DRM (corresponding to 392 DHA-rich oil*) (both M and F)	Hammond et al., 2001b

M = males; F = females. [a] FAs = fatty acids; *Conversion from DHA to DHA-rich oil quantity was based on the assumption that a typical DHA-rich oil used in various studies would contain 40% DHA.

6.B.4. Human Clinical Studies of DHA

All of the previous GRAS notices provided information/clinical study data that supported the safety of the proposed DHA ingredients for use in infant formula. In all of the studies summarized in these notifications, there were no significant adverse effects/events or tolerance issues in infants attributable to DHA-supplemented formulas when compared to the control-group infant formulas. Although these human clinical trials were not designed as safety studies the absence of adverse effects provide some evidence of the safe use of DHA-rich oils.

Due to bioequivalence of two types of algal DHA-rich oils (*Schizochytrium* sp. and *C. cohnii*), we have focused on the studies of infant formulas supplemented with DHA-rich oils from algal sources to make general conclusions about the safety of algal DHA-rich oil derived from *Schizochytrium* sp. In this review, it was assumed that unknown sources of algal DHA manufactured by Martek/DSM were derived from either *Schizochytrium* sp. or *C. cohnii.* All of the studies of algal DHA-rich oil reported no adverse events/effects on measured outcomes (Tables 15 to 18).

Studies of DHA in Adults (Table 15)

Daily doses of up to 2 g DHA from algal sources were not associated with treatment-related adverse effects on the measured outcomes (Molfino et al., 2017, 2019; Smith et al., 2018; MacDonald and Sieving, 2018). These studies measured DHA incorporation into RBC membranes and plasma tumor necrosis factor-alpha and interleukin-6 levels (Molfino et al., 2017), serum concentrations of epoxy-docosapentaenoic acids, metabolites of DHA in patients with BRCA1/2 gene mutation, patients with familiar positive history for breast cancer or sporadic breast cancer, and healthy controls (Molfino et al., 2019), the effects of DHA on depression, clinical severity and daytime sleepiness in patients with mild to moderate depression taking antidepressant medications who were non-responsive to medication or psychotherapy (Smith et al., 2018), and multifocal electroretinography (measures of retina function), visual acuity, DHA bioavailability, and adverse events in patients with macular disorder (MacDonald and Sieving, 2018).

In a study by Smith et al. (2018), the authors stated that ‘no significant adverse reactions to DHA were found’ although there was one case of rash and digestive discomfort, potentially related to DHA after 8 weeks of administration. In MacDonald and Sieving (2018), there were eight adverse events reported by four participants. All eight events were considered not related to DHA supplementation. Overall, doses up to 2 g/day were well tolerated with no side effects (Molfino et al., 2017, 2019; MacDonald and Sieving, 2018).

Studies in Children (Table 16)

In a study by Devlin et al. (2017), toddlers (mean age, 13.4 months) were randomized to receive DHA (200 mg/day; manufacturer-DSM; *Schizochytrium* source) and ARA (200 mg/day) (supplement) or a corn oil (control) until age 24 months. No adverse effects of DHA/ARA were

noted on cognitive development in healthy term toddlers. No other safety-related parameters were reported.

Studies of DHA in Pregnant Women and Offspring (Table 17)

Foster et al. (2017) evaluated the effect of DHA given during pregnancy to obese mothers on offspring adiposity. Mothers with gestational diabetes or obesity were randomized to receive DHA at 800 mg/day (manufacturer-DSM; DHASCO - algal type not specified) or placebo (corn/soy oil) starting at 25 - 29 weeks of gestation. Maternal RBC concentrations of DHA and ARA were measured at 26- and 36-week gestation and offspring adiposity measures were assessed at 2 and 4 years of age. No adverse effects of DHA were reported.

Carlson et al. (2018) reported that daily supplementation of 600 mg DHA to pregnant mothers during the last half of pregnancy had no adverse effects on maternal characteristics and birth outcomes. Kerling et al. (2019) and Hidaka et al. (2018) found that maternal DHA intake during pregnancy had no adverse effects on blood pressure of offspring at 4 to 6 years of age and on body composition including fat mass of children at age 5 years.

Overall, the review of recent human clinical trials is consistent with the conclusions of the previous GRAS notices (GRNs 137 and 732) that intake of DHA is safe as long as the daily intake does not exceed 1.5 g/person/day.

Studies of DHA in Term Infants (Table 18)

In the DHA Intake and Measurement of Neural Development (DIAMOND) study of Colombo et al. (2017), healthy term infants were enrolled at 1-9 days of age and were randomly assigned to be fed one of the following 4 infant formulas containing equivalent nutrient amounts for 12 months: control (0% DHA/0% ARA), 0.32, 0.64, or 0.96% of fatty acids as DHA (or up to 51 - 61 mg DHA/kg bw/day) derived from *C. cohnii.* All three DHA-supplemented formulas also provided 0.64% of fatty acids as ARA derived from *M. alpina*. The DHA levels correspond to daily intakes of up to 51 - 61 mg DHA/kg bw/day. The daily intake values of DHA were obtained based on the following assumptions: 1) infants consume about 100-120 kcal/kg bw/day. 2) 51 mg DHA/100 kcal was provided by the formula containing 0.96% DHA-rich oil (Colombo et al., 2017, page 3). 3) Infants consuming 100 kcal/kg bw/day will consume 51 mg DHA/kg bw/day (51 mg DHA/100 kcal x 100 kcal/kg bw/day=51 mg/kg bw/day), and those consuming 120 kcal/kg bw/day will consume 61 mg DHA/kg bw/day (51 mg DHA/100 kcal x 120 kcal/kg bw/day=61.2 mg/kg bw/day). DHA/ARA supplementation in the first year of life had no adverse effects on developmental outcome including sustained attention at 4, 6, and 9 months, function and problem-solving tasks at 36 to 72 months of age, verbal and composite IQ at 60 and 72 months, and RBC concentrations of DHA at 4 and 12 months of age.

From the same DIAMOND study, Lepping et al. (2019) reported that DHA/ARA supplementation in the first year of life had no adverse effects on cognitive performance, brain regions spontaneously function (connectivity between prefrontal and parietal regions of the

Dorsal Attention Network) and brain volume in various regions of the brain (gray and white matter volume) at the time of the 9-year follow-up.

Algal DHA, up to 0.96% of total fatty acids (or up to 61 mg DHA/kg bw/day), in combination with ARA (0.64% of fatty acids) was well tolerated, and no adverse effects were noted on the measured outcomes including tolerance, adverse events, growth, RBC concentrations of fatty acids, visual acuity, cognitive function, and/or school readiness.

Preterm Infants

Since June 2017, no new preterm infant studies with algal DHA were published. Previous GRAS notices reviewed the studies by Almaas et al. (2015, 2016) that tested the hypothesis that DHA/ARA supplementation in very low birth weight infants would influence cerebral white matter measured by diffusion tensor imaging (DTI) and behavioral and cognitive outcomes at 8 years of age. In these studies, human milk supplemented with 32 mg DHA (0.86% of total FAs as DHA; source not specified) and 31 mg ARA (0.91% of total FAs) per 100 mL was fed to preterm infants each day for 9 weeks after birth with an 8-year follow-up. It was designed that all infants would eventually receive the same amount of supplementation (100 mL) for 9 weeks. No adverse effects were reported on the measured outcomes.

Table 15. Adult Human Studies of DHA from Algal Sources*

Objective	Subject	Daily Dose	Duration	Measurements	Reference
To assess DHA incorporation in RBC membranes in breast cancer patients and in healthy controls	43 women: 11 women with BRCA 1/2 gene mutation, 12 women with family history of breast cancer, 10 women with sporadic breast cancer, 10 healthy women (control); mean ages 47.3-48.3 y	2 g/d DHA (Manufacturer-Dietetic Metabolic Food (DMF); from *Schizochytrium* sp.); no placebo group	10 d; before and after DHA.	DHA levels and Omega-3 Index in RBC membranes at baseline and after supplementation; serum concentrations of cytokines; self-reported dietary seafood consumption	Molfino et al., 2017
To measure serum concentrations of epoxydocosapentaenoic acids in breast cancer patients and in healthy controls				Serum concentrations of epoxy-docosapentaenoic acids, metabolites of the DHA	Molfino et al., 2019
To test if DHA dietary supplementation improves macular function in patients with a macular disorder	11 subjects (2 males, 9 females) with macular disorder; 26-63 y; median 40 y	0 or 2 g/d DHA (manufacturer-Martek/DSM; algae type, NA; 40% DHA)	3 mo.	Multifocal electroretinography (primary outcome -measures of retina function); visual acuity; serum DHA concentrations; adverse events	MacDonald and Sieving, 2018
To investigate if DHA provides additional adjunctive benefits in patients with mild to moderate depression taking antidepressant medication	28 patients with mild to moderate major depressive disorder who were non-responsive to medication or psychotherapy; mean age 49 y	260 or 520 mg DHA/d; (manufacturer-DSM; algae type, NA)	8 wk open-label pilot trial	Depression; clinical severity; daytime sleepiness; tolerance	Smith et al., 2018

*Excluding studies of DHA from fish oil source or DHA-ethyl ether; d = days; DHA = docosahexaenoic acid; mo = months; NA = not available; RBC = red blood cell; wk = weeks.

Table 16. Human Studies of DHA from Algal Sources in Toddlers and Children*

Objective	Subject	Dose	Duration	Measurements	Reference
To investigate the effects of DHA and ARA on cognitive development in toddlers	133 healthy term (37–41 weeks gestation) toddlers, mean age 13.4 mo	2 groups: DHA (200 mg/d) from DHASCO®-S oil (manufacturer-DSM, *Schizochytrium* sp. source) and ARA (DSM; 200 mg/day) supplement or a corn oil control	Until 24 mo of age	Bayley Scales of Infant and Toddler Development 3rd Edition (Bayley-III) cognitive and language composites and Beery–Buktenica Developmental Test of Visual–Motor Integration (Beery VMI) at 24 mo; circulating DHA and ARA levels: maternal intelligence	Devlin et al., 2017

*Excluding studies of DHA from fish oil source or DHA-ethyl ether; ARA = arachidonic acid; DHA = docosahexaenoic acid; mo = months.

Table 17. Human Studies of DHA from Algal Sources during Pregnancy and/or through Postpartum*

Objective	Subject	Dose	Duration	Measurements	Reference
To determine if DHA given during pregnancy to obese mothers results in lower offspring adiposity	72 women were enrolled at 25–29 weeks of gestation (mean 26.6 weeks); 92% Hispanic mothers; mean age 29.2 y	DHA (800 mg/d) supplementation (algal DHA oil from DSM, algae type-NA) or corn oil	Until delivery of babies; P	Maternal erythrocyte DHA and ARA levels at 26 and 36 wk gestation; 63 offspring – anthropometric measurements including adiposity at birth and 2 y and 4 y follow-up; the Bayley Scales of Infant and Toddler Development, Third Edition at 2 y of age; children's eating habit survey by mothers at 2 y and 4 y	Foster et al., 2017
To identify the effects of DHA supplementation during pregnancy on maternal characteristics and on the probability for having low and very low birth wt infants	345 pregnant mothers	Kansas University DHA Outcomes Study: DHA (600 mg/d) (algal DHA from DSM, algae type-NA) or placebo (corn and soybean mixture)	Beginning after 12 and before 20 wk gestation and continuing until the end of their pregnancy	Capsule compliance and maternal characteristics (education and age); capsule compliance and birth outcomes (early preterm birth, very low birth weight, and low birth weight)	Carlson et al., 2018
To determine the effect of DHA supplementation during pregnancy on childhood blood pressure	190 children of women who had participated in the Kansas University DHA Outcomes Study		Beginning 14.5 wk of gestation until delivery; Follow up of children at age 4 to 6 y	Offspring - blood pressure	Kerling et al., 2019
To determine the effect of prenatal DHA supplementation on childhood blood pressure	154 offspring of women who had participated in the Kansas University DHA		Beginning 14.5 wk of gestation until delivery; Follow up of	Maternal RBC and phospholipids and DHA status at delivery; change in maternal DHA; Offspring - 5-y body composition (fat mass, fat-free mass, percentage of body fat,	Hidaka et al., 2018

	Outcomes Study		children at age 5 y	height, weight, and body mass index *z* score)	
To determine the effect of prenatal DHA supplementation on childhood blood pressure	301 mothers in the initial study, ~200 infants completed the longitudinal schedule		Beginning 14.5 wk of gestation until delivery; Offspring - follow up at 10 to 72 mo of age	Mothers-blood DHA status during pregnancy; Offspring – verbal and full scale intelligence quotient scores	Colombo et al., 2019

*Excluding studies of DHA from fish oil source or DHA-ethyl ether; ARA = arachidonic acid; DHA = docosahexaenoic acid; d=days; NA = not available; RBC=red blood cell; wk=weeks; y = years.

Table 18. Human Studies of DHA from Algal Sources in Term-Infants*

Objective	Subject	Dose	Duration	Measurements	Reference
To investigate the DHA/ARA balance as an important variable on the cognitive and behavioral development in infancy	343 term infants, 2,490 and 4,200 g at birth	DHA Intake And Measurement of Neural Development (DIAMOND) study: 3 concentrations of DHA (derived from *C. cohnii*): 0.32, 0.64, or 0.96% of fatty acids as DHA (or 0, 17, 34, or 51 mg DHA/100 kcal) with a fixed conc. of 0.64% ARA (or 34 mg ARA/100 kcal; from *M. alpina*); or control - unsupplemented	Formula fed from birth for 12 mo; follow-up from birth to 6 y	Developmental outcome; sustained attention at 4, 6, and 9 mo; function and problem-solving tasks at 36 to 72 mo of age; verbal and composite IQ at 60 and 72 mo; RBC and ARA concentrations of DHA at 4 and 12 mo of age	Colombo et al., 2017
To investigate the effects of DHA/ARA supplementation in the first year of life on brain function, structure, and metabolism at 9 y of age	42 children aged about 9 y who participated in the DIAMOND study		Formula fed from birth for 12 mo; follow-up from birth to 9 y	Cognitive performance; brain regions spontaneous function; brain volume in various regions of the brain (white and gray matter volume)	Lepping et al., 2019

*Excluding studies of DHA from fish oil source or DHA-ethyl ether; ARA = arachidonic acid; DHA = docosahexaenoic acid; IQ = intelligence quotient; mo = months; RBC=red blood cell; y = years.

6.B.5. Potential Adverse Effects

The FDA raised concerns about the consumption of high levels of EPA and DHA, which may increase bleeding time, increase levels of LDL-C, and have an effect on glycemic control in subjects with type 2 diabetes (menhaden oil final rule; 62 FR 30751; June 5, 1997). To assure that the combined exposure to EPA and DHA would not exceed 3 g/person/day, the FDA established the maximum levels of use for menhaden oil that would be permitted in specified food categories [21 CFR 184.1472(a)(3)]. No studies on type 2 diabetics have reported increased glucose levels in plasma when higher amounts (4.5 to 6.9 g/person/day) of omega-3 fatty acids were ingested (Bucher et al., 2002; Buckley et al., 2004). Overall, our review of human clinical trials supports the ADI of 1.5 g/person/day for DHA in adults. No adverse effects of DHA in infant formula up to 0.96% of total fatty acids (51-61 mg DHA/kg bw/day) were reported.

6.C. Safety Determination

Numerous human and animal studies have reported health benefits of DHA with no major adverse effects. There is broad-based and widely disseminated knowledge concerning the chemistry of DHA-rich oil. This GRAS determination is based on the data and information generally available and consented opinion about the safety of DHA.

The following safety evaluations fully consider the composition, intake, and nutritional, microbiological, and toxicological properties of DHA-rich oil as well as appropriate corroborative data.

1. Analytical data from multiple lots indicate that DHA-rich oil reliably complies with established specifications and meets all applicable purity standards. Its purity is over 36.0% DHA. No significant amounts of domoic acid, mycotoxins, and other contaminants have been detected from Hubei Fuxing's DHA-rich oil.

2. As the DHA-rich oil in this GRAS notice has similar specifications and composition to those described in previous FDA GRAS notices, it is concluded that Hubei Fuxing's DHA-rich oil is substantially chemically equivalent to those described in GRNs 137, 553, 731, and in particular to that described in GRN 677. Thus, the information and data presented or reviewed in the GRN notices are pertinent when evaluating the safety of the DHA-rich oil in this GRAS notice. As noted above, the FDA did not question the safety of DHA-rich oils for the specified food uses in response to GRAS notifications on DHA-rich oil derived from *Schizochytrium* sp.

3. Hubei Fuxing's DHA-rich oil will be added to the same food categories as those currently listed in 21 CFR 184.1472(a)(3) (menhaden oil), excluding egg, meat, poultry, and fish products, at maximum use levels that are 27.78% of those specified in that regulation. Based on the final rule on menhaden oil described in 21 CFR 184.1472(a)(3), the ADI for DHA has been established as 1.5 g/person/day. In addition, algal DHA-rich oils derived from *Schizochytrium* sp. (GRNs 137 and 732) received FDA GRAS notice status to result in a maximum dietary exposure of less than 1.5 g of DHA per day. Furthermore, historical

consumption of DHA supports the safety of DHA as long as the consumption level does not exceed 1.5 g/person/day. Recently published studies continue to support the safety of DHA as a food ingredient.

4. Hubei Fuxing's DHA-rich oil may be used at a maximum use level of 0.5% of total fat as DHA or 1.39% of dietary fat as Hubei Fuxing's DHA-rich oil in infant formulas for term and preterm infants. The intended use will result in 27 to 33 mg DHA/kg bw/day or 75 to 93 mg DHA-rich oil/kg bw/day. This estimated DHA intake is consistent with current DHA recommendations for preterm and term infants of 18 to 60 mg/kg bw/day depending on gestational age. The intended use level is the same as other approved uses for incorporation of DHA-rich oils in infant formula for term and preterm infants (GRNs 553, 677, 731, and 776/777). Recently published studies continue to support the safety of DHA as a food ingredient for infants.

5. It is assumed that Hubei Fuxing's DHA-rich oil derived from *Schizochytrium* sp. will replace currently marketed DHA or other DHA sources. Thus, cumulative exposures are not expected to change.

6. In previous GRAS notices to the FDA, the safety of DHA has been established in toxicological studies in animals, and mutagenicity and genotoxicity studies, and is further supported by clinical studies in human. The NOAEL was determined to be 3,149 mg/kg bw/day in a subchronic toxicity study in rats. The EDIs under the intended use are far less than the estimated safe intake levels in infants.

6.D. Conclusions and General Recognition of the Safety of DHA-Rich Oil

6.D.1. Common Knowledge Element of the GRAS Determination

Several sources of DHA or DHA-rich oil derived from *Schizochytrium* sp. have been evaluated by the FDA over the past 16 years for the proposed incorporation of DHA in foods for human consumption. Relevant U.S. GRAS notifications include GRNs 137, 553, 677, 731/732, 776/777, 836, and 843/844 (FDA, 2004, 2015, 2017, 2018a-d, 2019a-c). All the GRAS notices provided information/clinical study data that supported the safety of the proposed DHA ingredients for use in human foods. In all the studies summarized in these notifications, there were no significant adverse effects/events or tolerance issues attributable to DHA. Due to the compositional similarity and DHA content of algae-derived oils to Hubei Fuxing's DHA-rich oil, the available scientific literature on the safety of these oils supports the safety of Hubei Fuxing's DHA-rich oil derived from *Schizochytrium* sp. Because this safety evaluation was based on generally available and widely accepted data and information, it satisfies the so-called "common knowledge" element of a GRAS determination.

6.D.2. Technical Element of the GRAS Determination (Safety Determination)

In addition, the intended uses of DHA have been determined to be safe though scientific procedures as set forth in 21 CFR 170.3(b); thus, satisfying the so-called "technical" element of the GRAS determination. The specifications and fatty acid profile of the proposed GRAS substance, Hubei Fuxing's DHA-rich oil derived from *Schizochytrium* sp. is substantially equivalent to those that have received FDA's 'no question' letters.

This GRAS determination for DHA is based on scientific procedures. Numerous human and animal studies examined safety-related parameters of DHA-rich oils. There are no reports of safety concerns in any of the studies as long as the consumption level does not exceed 1.5 g/person/day in the general population. In infants, no adverse effects of DHA in infant formula up to 0.96% of total fatty acids were reported.

Hubei Fuxing observes the principles of HACCP-controlled manufacturing process and cGMP and rigorously tests its final production batches to verify adherence to quality control specifications. The information and data provided by Hubei Fuxing in this report and supplemented by the publicly available literature/toxicity data on DHA and DHA-rich algal oil provide a sufficient basis for an assessment of the safety of DHA-rich oil from *Schizochytrium* sp. for the proposed use as an ingredient in food.

It is concluded that Hubei Fuxing's proposed use of DHA-rich oil is safe within the terms of the Federal Food, Drug, and Cosmetic Act (meeting the standard of reasonable certainty of no harm) and, thus, it is GRAS.

6.E. Discussion of Information Inconsistent with GRAS Determination

We are not aware of information that would be inconsistent with a finding that the proposed use of DHA, meeting appropriate specifications and used according to cGMP, is GRAS.

PART 7. REFERENCES

7.A. References That Are Generally Available

Abril R, Garrett J, Zeller SG, Sander WJ, Mast RW. Safety assessment of DHA-rich microalgae from *Schizochytrium* sp. Part V: Target animal safety/toxicity study in growing swine. Regul Toxicol Pharmacol. 2003;37:73-82.

Almaas AN, Tamnes CK, Nakstad B, Henriksen C, Walhovd KB, Fjell AM, Due-Tønnessen P, Drevon CA, Iversen PO. Long-chain polyunsaturated fatty acids and cognition in VLBW infants at 8 years: an RCT. Pediatrics. 2015;135:972-80.

Almaas AN, Tamnes CK, Nakstad B, Henriksen C, Grydeland H, Walhovd KB, Fjell AM, Iversen PO, Drevon CA. Diffusion tensor imaging and behavior in premature infants at 8 years of age, a randomized controlled trial with long-chain polyunsaturated fatty acids. Early Hum Dev. 2016;95:41-6.

Brenna JT, Varamini B, Jensen RG, Diersen-Schade DA, Boettcher JA, Arterburn LM. Docosahexaenoic and arachidonic acid concentrations in human breast milk worldwide. Am J Clin Nutr. 2007;85:1457-64.

Bucher HC, Hengstler P, Schindler C, Meier G. N-3 polyunsaturated fatty acids in coronary heart disease: a meta-analysis of randomized controlled trials. Am J Med. 2002;112:298-304.

Buckley R, Shewring B, Turner R, Yaqoob P, Minihane AM. Circulating triacylglycerol and apoE levels in response to EPA and docosahexaenoic acid supplementation in adult human subjects. Br J Nutr. 2004;92:477-83.

Carlson SE, Gajewski BJ, Alhayek S, Colombo J, Kerling EH, Gustafson KM. Dose-response relationship between docosahexaenoic acid (DHA) intake and lower rates of early preterm birth, low birth weight and very low birth weight. Prostaglandins Leukot Essent Fatty Acids. 2018;138:1-5.

Colombo J, Jill Shaddy D, Kerling EH, Gustafson KM, Carlson SE. Docosahexaenoic acid (DHA) and arachidonic acid (ARA) balance in developmental outcomes. Prostaglandins Leukot Essent Fatty Acids. 2017;121:52-6.

Colombo J, Shaddy DJ, Gustafson K, Gajewski BJ, Thodosoff JM, Kerling E, Carlson SE. The Kansas University DHA Outcomes Study (KUDOS) clinical trial: long-term behavioral follow-up of the effects of prenatal DHA supplementation. Am J Clin Nutr. 2019;109:1380-1392.

Devlin AM, Chau CMY, Dyer R, Matheson J, McCarthy D, Yurko-Mauro K, Innis SM, Grunau RE. Developmental outcomes at 24 months of age in toddlers supplemented with arachidonic acid and docosahexaenoic acid: Results of a double blind randomized, controlled trial. Nutrients. 2017;9(9). pii: E975.

Falk MC, Zheng X, Chen D, Jiang Y, Liu Z, Lewis KD. Developmental and reproductive toxicological evaluation of arachidonic acid (ARA)-rich oil and docosahexaenoic acid (DHA)-Rich oil. Food Chem Toxicol. 2017;103:270-8.

Food Chemicals Codex (FCC) online, 2018. 11th ed. https://www.foodchemicalscodex.org/.

Food and Drug Administration (FDA)**.** 1997. Substances affirmed as Generally Recognized as Safe: Menhaden oil; Final rule. Federal Reg. 62:30751.

FDA. 2004. Agency Response Letter. GRAS Notice No. GRN000137. Algal oil (Schizochytrium sp.). February 12, 2004. http://www.fda.gov/Food/FoodIngredientsPackanina/GenerallyRecognizedasSafeGRAS/GRAS Listingducm 153961.htm.

FDA. 2005. 21CFR 184.1472. Menhaden oil final rule (21 CFR, Part 184, Fed Reg (U.S.) 70 (55):14530-2.

FDA. 2015. Agency Response Letter. GRAS Notice No. GRN000553. Algal oil (40% docosahexaenoic acid) derived from *Schizochytrium* sp. June 19, 2015. https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm462744.htm.

FDA. 2017. Agency Response Letter. GRAS Notice No. GRN000677. Docosahexaenoic acid oil produced in *Schizochytrium* sp. May 2, 2017. https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM566347.pdf.

FDA. 2018a. Agency Response Letter. GRAS Notice No. GRN000731. Docosahexaenoic acid oil produced in *Schizochytrium* sp. April 6, 2018. https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM630673.pdf.

FDA. 2018b. Agency Response Letter. GRAS Notice No. GRN 000732. Docosahexaenoic acid oil produced in *Schizochytrium* sp. April 6, 2018. https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM630674.pdf.

FDA. 2018c. Agency Response Letter. GRAS Notice No. GRN000776. Algal oil (35% docosahexaenoic acid) from *Schizochytrium* sp. strain FCC-1324. October 26, 2018. https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm625983.pdf.

FDA. 2018d. Agency Response Letter. GRAS Notice No. GRN000777. Algal oil (55% docosahexaenoic acid) from *Schizochytrium* sp. strain FCC-3204. October 26, 2018. https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm625998.pdf.

FDA, 2019a. Agency Response Letter. GRAS Notice No. GRN000836. Algal oil (50-60% docosahexaenoic acid) from *Schizochytrium* sp. HS01. Sep 3, 2019. https://www.fda.gov/media/132031/download.

FDA, 2019b. Agency Response Letter. GRAS Notice No. GRN000843. Algal oil (35% docosahexaenoic acid) from *Schizochytrium* sp. strain FCC-1324. Oct 18, 2019. https://www.fda.gov/media/133204/download.

FDA, 2019c. Agency Response Letter. GRAS Notice No. GRN000844. Algal oil (55% docosahexaenoic acid) from *Schizochytrium* sp. strain FCC-3204. Oct 18, 2019. https://www.fda.gov/media/133205/download.

Fedorova-Dahms I, Marone PA, Bailey-Hall E, Ryan AS. Safety evaluation of algal oil from *Schizochytrium* sp. Food Chem Toxicol. 2011a;49:70-7.

Fedorova-Dahms I, Marone PA, Bauter M, Ryan AS. Safety evaluation of DHA-rich algal oil from *Schizochytrium* sp. Food Chem Toxicol. 2011b;49:3310-8.

Fedorova-Dahms I, Thorsrud BA, Bailey E, Salem N Jr. A 3-week dietary bioequivalence study in preweaning farm piglets of two sources of docosahexaenoic acid produced from two different organisms. Food Chem Toxicol. 2014;65:43-51.

Foster BA, Escaname E, Powell TL, Larsen B, Siddiqui SK, Menchaca J, Aquino C, Ramamurthy R, Hale DE. Randomized controlled trial of DHA supplementation during pregnancy: Child adiposity outcomes. Nutrients. 2017;9. pii: E566.

Hammond BG, Mayhew DA, Naylor MW, Ruecker FA, Mast RW, Sander WJ. Safety assessment of DHA-rich microalgae from *Schizochytrium* sp. I. Subchronic rat feeding study. Regul Toxicol Pharmacol. 2001a;33:192-204.

Hammond BG, Mayhew DA, Holson JF, Nemec MD, Mast RW, Sander WJ. Safety assessment of DHA-rich microalgae from *Schizochytrium* sp. II. Developmental toxicity evaluation in rats and Rabbits. Regul Toxicol Pharmacol. 2001b;33:205-17.

Hammond BG, Mayhew DA, Robinson K, Mast RW, Sander WJ. Safety assessment of DHA-rich microalgae from *Schizochytrium* sp. III. Single-generation rat reproduction study. Regul Toxicol Pharmacol. 2001c;33:356-62.

Hammond BG, Mayhew DA, Kier LD, Mast RW, Sander WJ. Safety assessment of DHA-rich microalgae from *Schizochytrium* sp. IV. Mutagenicity studies. Regul Toxicol Pharmacol. 2002;35:255-65.

Hidaka BH, Thodosoff JM, Kerling EH, Hull HR, Colombo J, Carlson SE. Intrauterine DHA exposure and child body composition at 5 y: exploratory analysis of a randomized controlled trial of prenatal DHA supplementation. Am J Clin Nutr. 2018;107:35-42.

Kerling EH, Hilton JM, Thodosoff JM, Wick J, Colombo J, Carlson SE. Effect of prenatal docosahexaenoic acid supplementation on blood pressure in children with overweight condition or obesity: A secondary analysis of a randomized clinical trial. JAMA Netw Open. 2019;2(2):e190088.

Koletzko B, Boey CC, Campoy C, Carlson SE, Chang N, Guillermo-Tuazon MA, Joshi S, Prell C, Quak SH, Sjarif DR, Su Y, Supapannachart S, Yamashiro Y, Osendarp SJ. Current information and Asian perspectives on long-chain polyunsaturated fatty acids in pregnancy, lactation, and infancy: systematic review and practice recommendations from an early nutrition academy workshop. Ann Nutr Metab. 2014;65:49-80.

Kremmyda LS, Tvrzicka E, Stankova B, Zak A. Fatty acids as biocompounds: Their role in human metabolism, health and disease: A review. part 2: Fatty acid physiological roles and applications in human health and disease. Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub. 2011;155:195-218.

Kroes R, Schaefer EJ, Squire RA, Williams GM. A review of the safety of DHA45-oil. Food Chem Toxicol. 2003;41:1433-46.

Lepping RJ, Honea RA, Martin LE, Liao K, Choi IY, Lee P, Papa VB, Brooks WM, Shaddy DJ, Carlson SE, Colombo J, Gustafson KM. Long-chain polyunsaturated fatty acid supplementation in the first year of life affects brain function, structure, and metabolism at age nine years. Dev Psychobiol. 2019;61:5-16.

Lewis KD, Huang W, Zheng X, Jiang Y, Feldman RS, Falk MC. Toxicological evaluation of arachidonic acid (ARA)-rich oil and docosahexaenoic acid (DHA)-rich oil. Food Chem Toxicol. 2016;96:133-44.

Martin JC, Bougnoux P, Antoine JM, Lanson M, Couet C. Triacylglycerol structure of human colostrum and mature milk. Lipids. 1993;28:637-43.

MacDonald IM, Sieving PA. Investigation of the effect of dietary docosahexaenoic acid (DHA) supplementation on macular function in subjects with autosomal recessive Stargardt macular dystrophy. Ophthalmic Genet. 2018;39:477-486.

Molfino A, Amabile MI, Mazzucco S, Biolo G, Farcomeni A, Ramaccini C, Antonaroli S, Monti M, Muscaritoli M. Effect of oral docosahexaenoic acid (DHA) supplementation on DHA levels and omega-3 index in red blood cell membranes of breast cancer patients. Front Physiol. 2017;8:549. doi: 10.3389/fphys.2017.00549. eCollection 2017.

Molfino A, Amabile MI, Lionetto L, Spagnoli A, Ramaccini C, De Luca A, Simmaco M, Monti M, Muscaritoli M. DHA oral supplementation modulates serum epoxydocosapentaenoic acid (EDP) levels in breast cancer patients. Oxid Med Cell Longev. 2019:1280987. doi: 10.1155/2019/1280987. eCollection 2019.

Schmitt D, Tran N, Peach J, Bauter M, Marone P. Toxicologic evaluation of DHA-rich algal oil: Genotoxicity, acute and subchronic toxicity in rats. Food Chem Toxicol. 2012a;50:3567-76.

Schmitt D, Tran N, Peach J, Edwards T, Greeley M. Toxicologic evaluations of DHA-rich algal oil in rats: Developmental toxicity study and 3-month dietary toxicity study with an *in utero* exposure phase. Food Chem Toxicol. 2012b;50:4149-57.

Smith DJ, Sarris J, Dowling N, O'Connor M, Ng CH. Adjunctive low-dose docosahexaenoic acid (DHA) for major depression: An open-label pilot trial. Nutr Neurosci. 2018;21:224-8.

Yeiser M, Harris CL, Kirchoff AL, Patterson AC, Wampler JL, Zissman EN, Berseth CL. Growth and tolerance of infants fed formula with a new algal source of docosahexaenoic acid: Double-blind, randomized, controlled trial. Prostaglandins Leukot Essent Fatty Acids. 2016;115:89-96.

7.B. Reference That Are Not Generally Available

Gao Y. 2019a. Mutagenicity Study of DHA-rich Oil. A report for NutraSource, Inc.. (Appendix C).

Gao Y. 2019b. Acute oral toxicity of DHA-rich Oil in rats. A report for NutraSource, Inc. . (Appendix D).

Appendix A. Certificates of Analysis

eurofins

Preliminary report

Page 1/7
PR-19-SU-000052-01

Analytical Report

Sample Code	502-2019-00010198	Report date	25-Mar-2019
Certificate No.	PR-19-SU-000052-01		

HuBei Fuxing Biotechnology CO,.LTD
Yanrong Wu
NO.18 Fuxing Street, Chenhu Town,
Hanchuan, Hubei, P.R. China
Fax 0086 0712-8741957

Our reference:	502-2019-00010198/ PR-19-SU-000052-01
Client Sample Code:	D18071101J
Sample described as:	DHA油脂
Sample Packaging:	Sealed metal bottle
Sample reception date:	20-Feb-2019
Analysis starting date:	20-Feb-2019
Analysis ending date:	22-Mar-2019
Arrival Temperature (°C)	17.6
Sample Weight	600g*2

		Results	Unit	LOQ	LOD
SU007	Mercury (AAS) Method: BS EN 13806:2002				
	Mercury (Hg)	<0.005	mg/kg	0.005	
SU061	Manganese (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Manganese (Mn)	<0.1	mg/kg	0.1	
SU066	Molybdenum (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Molybdenum (Mo)	<0.03	mg/kg	0.03	
SU066	Nickel (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Nickel (Ni)	<0.1	mg/kg	0.1	
SU06D	Lead (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Lead (Pb)	<0.05	mg/kg	0.05	
SU06E	Arsenic (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Arsenic (As)	<0.05	mg/kg	0.05	
SU06F	Chromium (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Chromium (Cr)	<0.1	mg/kg	0.1	
SU06G	Cadmium (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Cadmium (Cd)	<0.01	mg/kg	0.01	
SU06J	Copper (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Copper (Cu)	<0.1	mg/kg	0.1	
SU06K	Phosphorus (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Phosphorus (P)	41.4	mg/kg	5	
SU61B	Iron (ICP-OES) Method: Internal Method ICP-OES, ICP-OES				
	Iron (Fe)	<0.1	mg/100 g	0.1	

		Results	Unit	LOQ	LOD
SUS1A	Pesticide Screening(GC) Method: BS EN 12393:2013				
	Screened pesticides	<LOQ	mg/kg		

		Results	Unit	LOQ	LOD
SU10Z	Cronobacter spp. in 10g Method: ISO 22964:2017				
	Cronobacter spp	Not Detected	/10 g		

		Results	Unit	LOQ	LOD
SU20L	Protein Method: AOAC 984.13				

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 826 5088
Fax
www.eurofins.cn

eurofins TESTING SERVICE

eurofins

Preliminary report

		Results	Unit	LOQ	LOD
	Protein	<0.1 (k=6.25)	g/100 g	0.1	
SU217	Physical inspection Method: Internal Method, Organoleptic evaluation				
	Physical inspection	see attached document			
SU227	Ash Method: AOAC 941.12; AOAC 923.03				
	Ash	0.04	g/100 g	0.01	
SU372	Cholesterol Method: GB 5009.128-2016				
	Cholesterol	2381	mg/kg	10	

		Results	Unit	LOQ	LOD
☆ SF0XA	add 1 on to the GC/MS-pesticide screening Selected Parameter(s) Method: § 64 LFGB L 00.00-34 : 2010-09, mod.				
	Tralomethrin	<0.05	mg/kg	0.05	
☆ FL023	Plant sterols and plant stanols (not enriched) Method: NMKL 198:2014				
	Brassicasterol	15	mg/100 g	1	
	Cholesterol	210	mg/100 g	1	
	Campesterol	15	mg/100 g	1	
	Campestanol	1	mg/100 g	1	
	Stigmasterol	27	mg/100 g	1	
	Unidentified sterols	196	mg/100 g	1	
	Sitosterol	67	mg/100 g	1	
	Sitostanol+ delta-5-avenasterol	7	mg/100 g	1	
	Delta-5,24-stigmastadienol	10	mg/100 g	1	
	Delta-7-stigmastenol	28	mg/100 g	1	
	delta-7-Avenasterol	6	mg/100 g	1	
	Cycloartenol	2	mg/100 g	1	
	24-Methylenecycloartanol	2	mg/100 g	1	
	Citrostadienol	2	mg/100 g	1	
	Total plant sterols + plant stanols	372	mg/100 g	1	
☆ JC00V	PAH acc. to EU 208/2006 (15+1) Method: Internal, GC-MS				
	5-Methylchrysene	<1	µg/kg	1	
	Benz(a)anthracene	<0.5	µg/kg	0.5	
	Benzo(a)pyrene	<0.5	µg/kg	0.5	
	Benzo(b)fluoranthene	<0.5	µg/kg	0.5	
	Benzo-(c)-fluorene	<1	µg/kg	1	
	Benzo(g,h,i)perylene	<0.5	µg/kg	0.5	
	Benzo-(j)-fluoranthen	<0.5	µg/kg	0.5	
	Benzo(k)fluoranthene	<0.5	µg/kg	0.5	
	Chrysene	<0.5	µg/kg	0.5	
	Cyclopenta(c,d)pyrene	<1	µg/kg	1	
	Dibenz(a,h)anthracene	<0.5	µg/kg	0.5	
	Dibenzo(a,e)pyrene	<1	µg/kg	1	
	Dibenzo(a,h)pyrene	<1	µg/kg	1	
	Dibenzo(a,i)pyrene	<1	µg/kg	1	
	Dibenzo(a,l)pyrene	<1	µg/kg	1	
	Indeno(1,2,3-cd)pyrene	<0.5	µg/kg	0.5	
	Sum of all positive identified PAH	Inapplicable	µg/kg		
	Sum PAH 4	Inapplicable	µg/kg		
☆ JC0A9	Patulin (oil) Method: Internal, LC-MS/MS				
	Patulin	<5	µg/kg	5	
☆ JCAF2	Aflatoxins B1, B2, G1, G2 (fats, oils, lecithin, egg powder) Method: internal method based on EN 14123				
	Aflatoxin B1	<0.1	µg/kg	0.1	
	Aflatoxin B2	<0.1	µg/kg	0.1	
	Aflatoxin G1	<0.1	µg/kg	0.1	
	Aflatoxin G2	<0.1	µg/kg	0.1	

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 216000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

	Results	Unit	LOQ	LOD
Sum of all positive Aflatoxins	<0.4	µg/kg		
☆ JJW2Z Sterigmatocystin Method: Internal, LC-MS/MS				
Sterigmatocystin	<10	µg/kg	10	
☆ LW0XD Domoic acid, DA Method: In house method (210), LC-MS				
Amnesic Shellfish Poison, Domoic acid	<3.0	µg/g	3	
Amnesic Shellfish Poison, Domoic Acid	Not Detected			
☆ QA00F Peroxide Value Method: AOCS Cd 8-53				
Peroxide value	<0.1	meq/kg	0.1	
☆ QA00I Acid Value Method: AOCS Cd 3d-63				
Acid value (mg KOH/g)	0.52	mg KOH/g	0.06	
Free fatty acids (as oleic acid)	0.26	%	0.03	
☆ QA01L p-Anisidine Value Method: AOCS Cd 18-90				
p-Anisidine Value	5.6		1	
☆ QA02L Color (Lovibond Scale) Method: AOCS Cc 13e-92; ISO 15305				
Color, red scale, 1 inch cell path	1.0			
Color, yellow scale, 1 inch cell path	10			
☆ QA034 Fumonisins (IAC-LC-MSMS) Method: JAOAC, 92 (2), 496.				
Fumonisin (B1+B2+B3)	<30	µg/kg	30	
Fumonisin B1	<10	µg/kg	10	
Fumonisin B2	<10	µg/kg	10	
Fumonisin B3	<10	µg/kg	10	
☆ QA04E Residual Solvents (GC-MS) Method: AOCS Cg 4-94				
1,1,1-Trichloroethane	<0.2	mg/kg	0.2	
1,1,2-Trichloroethane	<0.2	mg/kg	0.2	
1,2-Dichloroethane	<0.5	mg/kg	0.5	
1,2-Dimethoxyethane	<1	mg/kg	1	
1-Butanol	<1	mg/kg	1	
2-Hexanone	<1	mg/kg	1	
Acetone	<1	mg/kg	1	
Benzene	<0.1	mg/kg	0.1	
Butyl acetate	<0.5	mg/kg	0.5	
Carbon tetrachloride	<0.5	mg/kg	0.5	
Chlorobenzene	<0.5	mg/kg	0.5	
Chloroform	<0.1	mg/kg	0.1	
Cyclohexane	<0.2	mg/kg	0.2	
Dichloromethane	<0.1	mg/kg	0.1	
Ethanol	<1	mg/kg	1	
Ethyl acetate	<1	mg/kg	1	
Heptane	<0.2	mg/kg	0.2	
Hexane (sum of n-hexane, iso and 3-methyl pentane)	<0.5	mg/kg	0.5	
Isopropanol	<1	mg/kg	1	
Methanol	<1	mg/kg	1	
Methyl Ethyl Ketone (MEK)	<0.2	mg/kg	0.2	
Methyl-tert-butylether (MTBE)	<0.2	mg/kg	0.2	
Tetralin	<5	mg/kg	5	
Toluene	<0.2	mg/kg	0.2	
Trichloroethylene	<0.1	mg/kg	0.1	
Xylenes (sum)	<0.2	mg/kg	0.2	
☆ QA062 Polychlorinated Biphenyls (Oils & Fats) Method: ASU L00.00-34				
PCB 1	<0.01	mg/kg	0.01	
PCB 101	<0.01	mg/kg	0.01	
PCB 104	<0.01	mg/kg	0.01	
PCB 105	<0.01	mg/kg	0.01	

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 216000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins Preliminary report

		Results	Unit	LOQ	LOD
	PCB 118	<0.01	mg/kg	0.01	
	PCB 126	<0.01	mg/kg	0.01	
	PCB 128	<0.01	mg/kg	0.01	
	PCB 138	<0.01	mg/kg	0.01	
	PCB 153	<0.01	mg/kg	0.01	
	PCB 170	<0.01	mg/kg	0.01	
	PCB 18	<0.01	mg/kg	0.01	
	PCB 180	<0.01	mg/kg	0.01	
	PCB 187	<0.01	mg/kg	0.01	
	PCB 188	<0.01	mg/kg	0.01	
	PCB 195	<0.01	mg/kg	0.01	
	PCB 201	<0.01	mg/kg	0.01	
	PCB 206	<0.01	mg/kg	0.01	
	PCB 209	<0.01	mg/kg	0.01	
	PCB 28	<0.01	mg/kg	0.01	
	PCB 29	<0.01	mg/kg	0.01	
	PCB 44	<0.01	mg/kg	0.01	
	PCB 50	<0.01	mg/kg	0.01	
	PCB 52	<0.01	mg/kg	0.01	
	PCB 66	<0.01	mg/kg	0.01	
	PCB 77	<0.01	mg/kg	0.01	
	PCB 8	<0.01	mg/kg	0.01	
	PCB 87	<0.01	mg/kg	0.01	
	Sum Non-Dioxin-Like PCBs (28+52+101+138+153+180)	<0.01	mg/kg	0.01	
	Total PCB	<0.1	mg/kg	0.1	
☆ QA0MT	Ochratoxin A (HPLC-FLD) Method: AOAC 2000.16				
	Ochratoxin A	<1	µg/kg	1	
☆ QA23L	Trans Fatty Acids, relative area % (GC-FID) Method: AOCS Ce 1f-96				
	Total Trans Fatty Acids	0.20	% of fatty acids	0.01	
	total trans fatty acids C18:1	<0.01	% of fatty acids	0.01	
	total trans fatty acids C18:2 (without CLA)	0.12	% of fatty acids	0.01	
	total trans fatty acids C18:2 + C18:3	0.20	% of fatty acids	0.01	
	total trans fatty acids C18:3	0.08	% of fatty acids	0.01	
☆ QA282	Free Fatty Acid, as Oleic Method: AOCS Ca 5a-40				
	Free fatty acids as oleic acid	0.18	%	0.01	
☆ QA328	Insoluble Impurities Method: AOCS Ca 3a-46				
	Insoluble impurities	<0.01	%	0.01	
☆ QA513	Toxaphene (GC-MSMS)				
	Toxaphene Parlar 26	<LOQ	mg/kg	0.01	
	Toxaphene Parlar 50	<LOQ	mg/kg	0.01	
	Toxaphene Parlar 62	Not Analyzable	mg/kg	0.01	
☆ QA560	Sulfallate (Vegedex)				
	Sulfallate (Vegedex)	<0.02	mg/kg	0.02	
☆ QA867	Silicon (ICP-AES) Method: AOCS Ca 17-01				
	Silicon (Si)	4.2	mg/kg	1	
☆ QA967	Unsaponifiable Matter (Ethyl ether ext) Method: AOCS Ca 6b-53				
	Unsaponifiable matter	1.66	%	0.05	
☆ QAA07	Vomitoxin (Deoxynivalenol, DON) LC-MSMS Method: Food Addit Contam Part A, 2013:30(3),541-9.				

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

	Results	Unit	LOQ	LOD
Vomitoxin (Deoxynivalenol)	<50	µg/kg	50	
☆ QAA19 Zearalenone (LC-MSMS) Method: Food Addit Contam Part A, 2013:30(3),641-9.				
Zearalenone	<25	µg/kg	25	
☆ QD089 Fatty Acids-Omega 6 & 3 %W/W Method: AOCS Ce 2-66 AOCS Ce 1-62				
C08:0 Octanoic (Caprylic)	<0.02	%	0.02	
C10:0 Decanoic (Capric)	<0.02	%	0.02	
C11:0 Undecanoic (Hendecanoic)	<0.02	%	0.02	
C12:0 Dodecanoic (Lauric)	0.04	%	0.02	
C14:0 Tetradecanoic (Myristic)	0.46	%	0.02	
C14:1 Tetradecenoic (Myristoleic)	0.02	%	0.02	
C15:0 Pentadecanoic	0.79	%	0.02	
C15:1 Pentadecenoic	<0.02	%	0.02	
C16:0 Hexadecanoic (Palmitic)	22.24	%	0.02	
C16:1 Hexadecenoic (Palmitoleic)	0.15	%	0.02	
C16:2 Hexadecadienoic	<0.02	%	0.02	
C16:3 Hexadecatrienoic	<0.02	%	0.02	
C16:4 Hexadecatetraenoic	<0.02	%	0.02	
C17:0 Heptadecanoic (Margaric)	0.97	%	0.02	
C17:1 Heptadecenoic (Margaroleic)	0.02	%	0.02	
C18:0 Octadecanoic (Stearic)	1.23	%	0.02	
C18:1 Octadecenoic (Oleic + isomers)	3.25	%	0.02	
C18:2 Octadecadienoic (Linoleic + isomers)	6.84	%	0.02	
C18:2 Octadecadienoic Omega 6 (Linoleic)	6.82	%	0.02	
C18:3 Octadecatrienoic (Linolenic + isomers)	0.84	%	0.02	
C18:3 Octadecatrienoic Omega 3 (Alpha Linolenic)	0.75	%	0.02	
C18:3 Octadecatrienoic Omega 6 (Gamma Linolenic)	0.10	%	0.02	
C18:4 Octadecatetraenoic Omega 3 (Stearidonic)	0.10	%	0.02	
C20:0 Eicosanoic (Arachidic)	0.26	%	0.02	
C20:1 Eicosenoic (Gondoic + isomers)	0.03	%	0.02	
C20:2 Eicosadienoic Omega 6	0.03	%	0.02	
C20:3 Eicosatrienoic	0.22	%	0.02	
C20:3 Eicosatrienoic Omega 3	<0.02	%	0.02	
C20:3 Eicosatrienoic Omega 6	0.22	%	0.02	
C20:4 Eicosatetraenoic (Arachidonic + isomers)	0.90	%	0.02	
C20:4 Eicosatetraenoic Omega 3	0.49	%	0.02	
C20:4 Eicosatetraenoic Omega 6 (Arachidonic)	0.41	%	0.02	
C20:5 Eicosapentaenoic Omega 3	0.19	%	0.02	
C21:5 Heneicosapentaenoic Omega 3	<0.02	%	0.02	
C22:0 Docosanoic (Behenic)	0.15	%	0.02	
C22:1 Docosenoic (Erucic + isomers)	<0.02	%	0.02	
C22:2 Docosadienoic Omega 6	<0.02	%	0.02	
C22:3 Docosatrienoic, Omega 3	<0.02	%	0.02	
C22:4 Docosatetraenoic Omega 6	0.05	%	0.02	
C22:5 Docosapentaenoic	10.62	%	0.02	
C22:5 Docosapentaenoic Omega 3	0.05	%	0.02	
C22:5 Docosapentaenoic Omega 6	10.58	%	0.02	

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 216000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

	Results	Unit	LOQ	LOD
C22:6 Docosahexaenoic Omega 3	38.24	%	0.02	
C24:0 Tetracosanoic (Lignoceric)	<0.02	%	0.02	
C24:1 Tetracosenoic (Nervonic)	<0.02	%	0.02	
Sum of Omega 3 Isomers	39.82	%	0.06	
Sum of Omega 6 Isomers	18.21	%	0.06	
Total Fat as Triglycerides	91.43	%	0.1	
Total Fatty Acids Calc.	87.69	%	0.1	
Total Monounsaturated Fatty Acids	3.48	%	0.06	
Total Polyunsaturated Fatty Acids	58.06	%	0.06	
Total Saturated Fatty Acids	26.16	%	0.06	
☆ QD163 Moisture by Karl Fischer Method: AOCS Ca 2e-84				
Moisture, Karl Fischer	0.02	%	0.01	
☆ SFFED Pesticide screening using LC/MS/MS in fatty food Selected Parameter(s) Method: § 64 LFGB L 13.04-6 : 2013-08, mod.				
Linuron	<0.01	mg/kg	0.01	
Bromacil	<0.01	mg/kg	0.01	
Pyrethrins	<0.1	mg/kg	0.1	
☆ UMBYM Yeast-Mould E <10 >1500 /g (1) PCCG-P AOAC 997.02 Method: AOAC 997.02				
Moulds	<10	cfu/g		
Yeast	<10	cfu/g		
☆ UMCP8 Salmonella D Abs Pres /25 ml AOAC-RI 121501 Method: AOAC-RI 121501				
Salmonella	Not Detected	/25 ml		
☆ UMM1D Coliforms /ml AOAC 991.14 Method: AOAC 991.14				
Coliforms	<10	cfu/ml		

COMMENT

The content of total plant sterols and plant stanols does not contain cholesterol and non-4-desmethyl sterols (i.e. cycloartenol, 24-methylenecycloartanol, and citrostadienol).

Amount of total GC-eutables is 0,818 mg/100 g.

List of screened molecules (* = limit of quantification)

SUS1A **Pesticide Screening(GC) (LOQ* mg/kg)**

(a) 2-Phenylphenol (0.01)	(a) Acetochlor (0.05)	(a) Aclonifen (0.05)	(a) Aldrin (0.01)	(a) Ametryne (0.02)	(a) Aramite (0.04)
(a) Atrazine (0.02)	(a) Benfluralin (0.01)	(a) Bifenox (0.05)	(a) Bifenthrin (0.01)	(a) Biphenyl (0.01)	(a) Bromfenvinfos (0.02)
(a) Bromophos (0.01)	(a) Bromophos-ethyl (0.01)	(a) Bromopropylate (0.01)	(a) Butachlor (0.01)	(a) Butafenacil (0.01)	(a) Cadusafos (0.02)
(a) Captafol (0.05)	(a) Captan (0.05)	(a) Captan/THPI (Sum calculated as Captan) ()	(a) Carbophenothion (0.05)	(a) Carbophenothion-methyl (0.05)	(a) Carboxin (0.05)
(a) Chlorbenside (0.05)	(a) Chlordane (Sum) ()	(a) Chlordane, alpha (0.01)	(a) Chlordane, gamma (0.01)	(a) Chlorfenapyr (0.05)	(a) Chlorfenson (0.05)
(a) Chlorfenvinphos (0.01)	(a) Chlormephos (0.05)	(a) Chlorobenzilate (0.01)	(a) Chloroneb (0.01)	(a) Chloropropylate (0.01)	(a) Chlorothalonil (0.01)
(a) Chlorpyrifos (-ethyl) (0.01)	(a) Chlorpyrifos-methyl (0.01)	(a) Chlorthal-dimethyl (0.01)	(a) Chlorthion (0.05)	(a) Chlozolinate (0.02)	(a) Crufomate (0.05)
(a) Cyanazine (0.02)	(a) Cyanofenphos (0.05)	(a) Cyanophos (0.02)	(a) Cyfluthrin (0.05)	(a) Cyhalothrin, lambda-(incl. Cyhalothrin, gamma-) (0.01)	(a) Cypermethrin (0.05)
(a) Cyphenothrin (0.05)	(a) DDD, o,p'- (0.01)	(a) DDD, p,p'- (0.01)	(a) DDE, o,p'- (0.01)	(a) DDE, p,p'- (0.01)	(a) DDT (Sum) ()
(a) DDT, o,p'- (0.01)	(a) DDT, p,p'- (0.01)	(a) Deltamethrin (0.05)	(a) Dichlobenil (0.05)	(a) Dichlofenthion (0.02)	(a) Dichlofluanid (0.02)
(a) Dichlorobenzophenone o,p' (0.02)	(a) Dichlorobenzophenone p,p' (0.02)	(a) Dichlorvos (0.05)	(a) Dicloran (0.05)	(a) Dicofol (Sum) ()	(a) Dicofol, o,p'- (0.02)
(a) Dicofol, p,p'- (0.02)	(a) Dieldrin (0.02)	(a) Dieldrin (Sum) ()	(a) Dienochlor (0.05)	(a) Dinobuton (0.05)	(a) Dioxabenzofos (0.02)
(a) Dioxathion (0.05)	(a) Diphenylamine (0.01)	(a) Edifenphos (0.02)	(a) Endosulfan (Sum) ()	(a) Endosulfan, alpha- (0.05)	(a) Endosulfan, beta- (0.05)
(a) Endosulfan, sulfat- (0.02)	(a) Endrin (0.05)	(a) EPN (0.05)	(a) Ethalfluralin (0.01)	(a) Ethion (0.02)	(a) Etridiazole (0.02)
(a) Etrimfos (0.02)	(a) Fenamiphos (0.05)	(a) Fenchlorphos (0.02)	(a) Fenchlorphos (sum) ()	(a) Fenchlorphos oxon (0.01)	(a) Fenfluthrin (0.01)
(a) Fenitrothion (0.02)	(a) Fenpropathrin (0.02)	(a) Fenson (0.02)	(a) Fenthion (0.02)	(a) Fenvalerate & Esfenvalerate (Sum of RS&SR isomers) (0.02)	(a) Fenvalerate & Esfenvalerate(sum of RR,SS,RS,SR) ()
(a) Fenvalerate & Esfenvalerate(Sum of RR&SS isomers) (0.02)	(a) Fluchloralin (0.05)	(a) Flucythrinate (0.05)	(a) Flumetralin (0.05)	(a) Fluotrimazole (0.01)	(a) Fluquinconazole (0.02)
(a) Fluvalinate-tau (0.02)	(a) Fonofos (0.02)	(a) Formothion (0.05)	(a) HCB (0.01)	(a) HCH gamma(Lindan) (0.01)	(a) HCH, alpha- (0.01)
(a) HCH, beta- (0.01)	(a) HCH, delta- (0.01)	(a) HCH, epsilon- (0.01)	(a) Heptachlor (0.01)	(a) Heptachlor (Sum) ()	(a) Heptachlor epoxide cis (0.01)
(a) Heptachlor epoxide trans (0.01)	(a) Heptenophos (0.02)	(a) Iprobenfos (0.02)	(a) Isazofos (0.01)	(a) Isocarbophos (0.02)	(a) Isodrin (0.02)
(a) Isofenphos (0.02)	(a) Isofenphos-methyl (0.01)	(a) Isoprothiolane (0.02)	(a) Jodfenphos (0.02)	(a) Kresoxim-methyl (0.01)	(a) Landrin (0.02)
(a) Malaoxon (0.05)	(a) Malathion (0.02)	(a) Malathion (Sum) ()	(a) Mecarbam (0.04)	(a) Mepronil (0.01)	(a) Methacrifos (0.02)
(a) Methamidophos (0.1)	(a) Methidathion (0.02)	(a) Methoxychlor (0.02)	(a) Methyl-Pentachlorophenylsulfide (0.05)	(a) Metribuzin (0.04)	(a) Mevinphos (0.02)
(a) Mirex (0.01)	(a) N-Desethyl-pirimiphos-methyl (0.01)	(a) Nitrapyrin (0.01)	(a) Nitrofen (0.02)	(a) Nitrothal-isopropyl (0.01)	(a) Octachlorodipropyl ether (S-421) (0.05)
(a) Ofurace (0.01)	(a) Oxadiazon (0.02)	(a) Oxychlordane (0.02)	(a) Oxyfluorfen (0.02)	(a) Paclobutrazol (0.01)	(a) Parathion (0.01)
(a) Parathion-methyl (0.04)	(a) PCB 101 (0.01)	(a) PCB 118 (0.01)	(a) PCB 138 (0.01)	(a) PCB 153 (0.01)	(a) PCB 180 (0.01)
(a) PCB 28 (0.01)	(a) PCB 52 (0.01)	(a) Pentachloroaniline (0.01)	(a) Pentachloroanisole (0.01)	(a) Pentachlorobenzene (0.01)	(a) Permethrin (0.02)
(a) Phenkapton (0.05)	(a) Phenothrin (0.01)	(a) Phenthoate (0.02)	(a) Phorate (0.04)	(a) Phosphamidon (0.04)	(a) Picoxystrobin (0.01)
(a) Piperophos (0.01)	(a) Pirimiphos-ethyl (0.01)	(a) Procymidone (0.01)	(a) Profenofos (0.01)	(a) Profluralin (0.02)	(a) Prometryn (0.02)
(a) Propanil (0.01)	(a) Propazine (0.01)	(a) Prothiofos (0.02)	(a) Pyrazophos (0.01)	(a) Pyridalyl (0.05)	(a) Pyridaphenthion (0.02)
(a) Pyrifenox (0.04)	(a) Pyrimethanil (0.01)	(a) Quinalphos (0.01)	(a) Quintozene (0.01)	(a) Quizalofop-P-ethyl (0.01)	(a) Silafluofen (0.05)

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins TESTING SERVICE

eurofins

Preliminary report

(a) Silthiofam (0.01)	(a) Tebufenpyrad (0.01)	(a) Tecnazene (0.02)	(a) Tefluthrin (0.02)	(a) Terbufos (0.02)	(a) Tetrachlorvinphos (0.02)
(a) Tetradifon (0.02)	(a) Tetrahydrophthalimide (THPI) (0.06)	(a) Tetramethrin (0.02)	(a) Tetraval (0.01)	(a) Tolylfluanid (0.02)	(a) Triallate (0.02)
(a) Triazamate (0.01)	(a) Triazophos (0.02)	(a) Trichloronat (0.01)	(a) Trifluralin (0.02)	(a) Triticonazole (0.01)	(a) Uniconazole (0.02)
(a) Vinclozolin (0.02)					

SIGNATURE

Claire Wang
Authorized Signatory

Shine Xie
Authorized Signatory

EXPLANATORY NOTE

LOQ: Limit of Quantification
< LOQ: Below Limit of Quantification
N/A means Not applicable
+ CNAS # DAKKS ^CMA
☆ means the test is subcontracted within Eurofins group
° means the test is subcontracted outside Eurofins group

Sum compounds results are calculated from the results of each quantified compound as set by regulation
The result(s) relate(s) only to the item(s) tested and is(are) only for internal use by the client and not for publicly available as evidence.
This analytical report shall not be reproduced except in full, without written approval of the laboratory.
Eurofins General Terms and Conditions apply.
For and on behalf of Eurofins Technology Service (Suzhou) Co., Ltd

END OF REPORT

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 216000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Certificate No.: PR-19-SU-000052-01

Physical inspection

Sample code	502-2019-00010198
Sample name	DHA oil
Color	Light yellow
Odor	Have the special odor of this product
Texture	Oily liquid

Eurofins Tech. Service (Suzhou) Co. Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax +86 512 6878 5966
www.eurofins.cn

eurofins

Preliminary report

Analytical Report

Sample Code	502-2019-00010197	Report date	25-Mar-2019
Certificate No.	PR-19-SU-000051-01		

HuBei Fuxing Biotechnology CO,.LTD
Yanrong Wu
NO.18 Fuxing Street, Chenhu Town,
Hanchuan, Hubei, P.R. China
Fax 0086 0712-8741957

Our reference:	502-2019-00010197/ PR-19-SU-000051-01
Client Sample Code:	D18081801J
Sample described as:	DHA鱼油
Sample Packaging:	Sealed metal bottle
Sample reception date:	20-Feb-2019
Analysis starting date:	20-Feb-2019
Analysis ending date:	22-Mar-2019
Arrival Temperature (°C)	17.6
Sample Weight	600g*2

		Results	Unit	LOQ	LOD
SU007	Mercury (AAS) Method: BS EN 13806:2002				
	Mercury (Hg)	<0.005	mg/kg	0.005	
SU051	Manganese (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Manganese (Mn)	<0.1	mg/kg	0.1	
SU056	Molybdenum (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Molybdenum (Mo)	<0.03	mg/kg	0.03	
SU056	Nickel (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Nickel (Ni)	<0.1	mg/kg	0.1	
SU06D	Lead (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Lead (Pb)	<0.05	mg/kg	0.05	
SU06E	Arsenic (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Arsenic (As)	<0.05	mg/kg	0.05	
SU06F	Chromium (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Chromium (Cr)	<0.1	mg/kg	0.1	
SU06G	Cadmium (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Cadmium (Cd)	<0.01	mg/kg	0.01	
SU06J	Copper (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Copper (Cu)	<0.1	mg/kg	0.1	
SU06K	Phosphorus (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Phosphorus (P)	45.6	mg/kg	5	
SU61B	Iron (ICP-OES) Method: Internal Method ICP-OES, ICP-OES				
	Iron (Fe)	<0.1	mg/100 g	0.1	

		Results	Unit	LOQ	LOD
SUS1A	Pesticide Screening(GC) Method: BS EN 12393:2013				
	Screened pesticides	<LOQ	mg/kg		

		Results	Unit	LOQ	LOD
SU10Z	Cronobacter spp. in 10g Method: ISO 22964:2017				
	Cronobacter spp	Not Detected	/10 g		

		Results	Unit	LOQ	LOD
SU20L	Protein Method: AOAC 984.13				

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

		Results	Unit	LOQ	LOD
	Protein	<0.1 (k=6.25)	g/100 g	0.1	
SU217	Physical inspection Method: Internal Method, Organoleptic evaluation				
	Physical inspection	see attached document			
SU227	Ash Method: AOAC 941.12; AOAC 923.03				
	Ash	0.03	g/100 g	0.01	
SU372	Cholesterol Method: GB 5009.128-2016				
	Cholesterol	1234	mg/kg	10	

		Results	Unit	LOQ	LOD
☆ SF0XA	add 1 on to the GC/MS-pesticide screening Selected Parameter(s) Method: § 64 LFGB L 00.00-34 : 2010-09, mod.				
	Tralomethrin	<0.05	mg/kg	0.05	
☆ FL023	Plant sterols and plant stanols (not enriched) Method: NMKL 198:2014				
	Brassicasterol	9	mg/100 g	1	
	Cholesterol	113	mg/100 g	1	
	Campesterol	5	mg/100 g	1	
	Campestanol	1	mg/100 g	1	
	Stigmasterol	10	mg/100 g	1	
	Unidentified sterols	115	mg/100 g	1	
	Sitosterol	23	mg/100 g	1	
	Sitostanol+ delta-5-avenasterol	5	mg/100 g	1	
	Delta-5,24-stigmastadienol	4	mg/100 g	1	
	Delta-7-stigmastenol	13	mg/100 g	1	
	delta-7-Avenasterol	1	mg/100 g	1	
	Cycloartenol	2	mg/100 g	1	
	24-Methylenecycloartanol	3	mg/100 g	1	
	Citrostadienol	1	mg/100 g	1	
	Total plant sterols + plant stanols	186	mg/100 g	1	
☆ JC00V	PAH acc. to EU 208/2006 (15+1) Method: Internal, GC-MS				
	5-Methylchrysene	<1	µg/kg	1	
	Benz(a)anthracene	<0.5	µg/kg	0.5	
	Benzo(a)pyrene	<0.5	µg/kg	0.5	
	Benzo(b)fluoranthene	<0.5	µg/kg	0.5	
	Benzo-(c)-fluorene	<1	µg/kg	1	
	Benzo(g,h,i)perylene	<0.5	µg/kg	0.5	
	Benzo-(j)-fluoranthen	<0.5	µg/kg	0.5	
	Benzo(k)fluoranthene	<0.5	µg/kg	0.5	
	Chrysene	<0.5	µg/kg	0.5	
	Cyclopenta(c,d)pyrene	<1	µg/kg	1	
	Dibenz(a,h)anthracene	<0.5	µg/kg	0.5	
	Dibenzo(a,e)pyrene	<1	µg/kg	1	
	Dibenzo(a,h)pyrene	<1	µg/kg	1	
	Dibenzo(a,i)pyrene	<1	µg/kg	1	
	Dibenzo(a,l)pyrene	<1	µg/kg	1	
	Indeno(1,2,3-cd)pyrene	<0.5	µg/kg	0.5	
	Sum of all positive identified PAH	Inapplicable	µg/kg		
	Sum PAH 4	Inapplicable	µg/kg		
☆ JC0A9	Patulin (oil) Method: Internal, LC-MS/MS				
	Patulin	<5	µg/kg	5	
☆ JCAF2	Aflatoxins B1, B2, G1, G2 (fats, oils, lecithin, egg powder) Method: internal method based on EN 14123				
	Aflatoxin B1	<0.1	µg/kg	0.1	
	Aflatoxin B2	<0.1	µg/kg	0.1	
	Aflatoxin G1	<0.1	µg/kg	0.1	
	Aflatoxin G2	<0.1	µg/kg	0.1	

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

	Results	Unit	LOQ	LOD
Sum of all positive Aflatoxins	<0.4	µg/kg		
☆ JJW2Z Sterigmatocystin Method: Internal, LC-MS/MS				
Sterigmatocystin	<10	µg/kg	10	
☆ LW0XD Domoic acid, DA Method: In house method (210), LC-MS				
Amnesic Shellfish Poison, Domoic acid	<3.0	µg/g	3	
Amnesic Shellfish Poison, Domoic Acid	Not Detected			
☆ QA00F Peroxide Value Method: AOCS Cd 8-53				
Peroxide value	2.1	meq/kg	0.1	
☆ QA00I Acid Value Method: AOCS Cd 3d-63				
Acid value (mg KOH/g)	0.34	mg KOH/g	0.05	
Free fatty acids (as oleic acid)	0.17	%	0.01	
☆ QA01L p-Anisidine Value Method: AOCS Cd 18-90				
p-Anisidine Value	1.7		1	
☆ QA02L Color (Lovibond Scale) Method: AOCS Cc 13e-92; ISO 15305				
Color, red scale, 1 inch cell path	0.9			
Color, yellow scale, 1 inch cell path	9			
☆ QA034 Fumonisins (IAC-LC-MSMS) Method: JAOAC, 92 (2), 496.				
Fumonisin (B1+B2+B3)	<30	µg/kg	30	
Fumonisin B1	<10	µg/kg	10	
Fumonisin B2	<10	µg/kg	10	
Fumonisin B3	<10	µg/kg	10	
☆ QA04E Residual Solvents (GC-MS) Method: AOCS Cg 4-94				
1,1,1-Trichloroethane	<0.2	mg/kg	0.2	
1,1,2-Trichloroethane	<0.2	mg/kg	0.2	
1,2-Dichloroethane	<0.5	mg/kg	0.5	
1,2-Dimethoxyethane	<1	mg/kg	1	
1-Butanol	<1	mg/kg	1	
2-Hexanone	<1	mg/kg	1	
Acetone	<1	mg/kg	1	
Benzene	<0.1	mg/kg	0.1	
Butyl acetate	<0.5	mg/kg	0.5	
Carbon tetrachloride	<0.5	mg/kg	0.5	
Chlorobenzene	<0.5	mg/kg	0.5	
Chloroform	<0.1	mg/kg	0.1	
Cyclohexane	<0.2	mg/kg	0.2	
Dichloromethane	<0.1	mg/kg	0.1	
Ethanol	<1	mg/kg	1	
Ethyl acetate	<1	mg/kg	1	
Heptane	<0.2	mg/kg	0.2	
Hexane (sum of n-hexane, iso and 3-methyl pentane)	<0.5	mg/kg	0.5	
Isopropanol	<1	mg/kg	1	
Methanol	<1	mg/kg	1	
Methyl Ethyl Ketone (MEK)	<0.2	mg/kg	0.2	
Methyl-tert-butylether (MTBE)	<0.2	mg/kg	0.2	
Tetralin	<5	mg/kg	5	
Toluene	<0.2	mg/kg	0.2	
Trichloroethylene	<0.1	mg/kg	0.1	
Xylenes (sum)	<0.2	mg/kg	0.2	
☆ QA052 Polychlorinated Biphenyls (Oils & Fats) Method: ASU L00.00-34				
PCB 1	<0.01	mg/kg	0.01	
PCB 101	<0.01	mg/kg	0.01	
PCB 104	<0.01	mg/kg	0.01	
PCB 105	<0.01	mg/kg	0.01	

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 216000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

	Results	Unit	LOQ	LOD
PCB 118	<0.01	mg/kg	0.01	
PCB 126	<0.01	mg/kg	0.01	
PCB 128	<0.01	mg/kg	0.01	
PCB 138	<0.01	mg/kg	0.01	
PCB 153	<0.01	mg/kg	0.01	
PCB 170	<0.01	mg/kg	0.01	
PCB 18	<0.01	mg/kg	0.01	
PCB 180	<0.01	mg/kg	0.01	
PCB 187	<0.01	mg/kg	0.01	
PCB 188	<0.01	mg/kg	0.01	
PCB 195	<0.01	mg/kg	0.01	
PCB 201	<0.01	mg/kg	0.01	
PCB 206	<0.01	mg/kg	0.01	
PCB 209	<0.01	mg/kg	0.01	
PCB 28	<0.01	mg/kg	0.01	
PCB 29	<0.01	mg/kg	0.01	
PCB 44	<0.01	mg/kg	0.01	
PCB 50	<0.01	mg/kg	0.01	
PCB 52	<0.01	mg/kg	0.01	
PCB 66	<0.01	mg/kg	0.01	
PCB 77	<0.01	mg/kg	0.01	
PCB 8	<0.01	mg/kg	0.01	
PCB 87	<0.01	mg/kg	0.01	
Sum Non-Dioxin-Like PCBs (28+52+101+138+153+180)	<0.01	mg/kg	0.01	
Total PCB	<0.1	mg/kg	0.1	
☆ QA0MT Ochratoxin A (HPLC-FLD) Method: AOAC 2000.16				
Ochratoxin A	<1	µg/kg	1	
☆ QA23L Trans Fatty Acids, relative area % (GC-FID) Method: AOCS Ce 1f-96				
Total Trans Fatty Acids	0.12	% of fatty acids	0.01	
total trans fatty acids C18:1	<0.01	% of fatty acids	0.01	
total trans fatty acids C18:2 (without CLA)	0.12	% of fatty acids	0.01	
total trans fatty acids C18:2 + C18:3	0.12	% of fatty acids	0.01	
total trans fatty acids C18:3	<0.01	% of fatty acids	0.01	
☆ QA282 Free Fatty Acid, as Oleic Method: AOCS Ca 5a-40				
Free fatty acids as oleic acid	0.18	%	0.01	
☆ QA328 Insoluble Impurities Method: AOCS Ca 3a-46				
Insoluble impurities	<0.01	%	0.01	
☆ QA513 Toxaphene (GC-MSMS)				
Toxaphene Parlar 26	<LOQ	mg/kg	0.01	
Toxaphene Parlar 50	<LOQ	mg/kg	0.01	
Toxaphene Parlar 62	Not Analyzable	mg/kg	0.01	
☆ QA560 Sulfallate (Vegedex)				
Sulfallate (Vegedex)	<0.02	mg/kg	0.02	
☆ QA867 Silicon (ICP-AES) Method: AOCS Ca 17-01				
Silicon (Si)	<1	mg/kg	1	
☆ QA967 Unsaponifiable Matter (Ethyl ether ext) Method: AOCS Ca 6b-53				
Unsaponifiable matter	1.04	%	0.05	
☆ QAA07 Vomitoxin (Deoxynivalenol, DON) LC-MSMS Method: Food Addit Contam Part A, 2013;30(3),541-9.				

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

	Results	Unit	LOQ	LOD
Vomitoxin (Deoxynivalenol)	<50	µg/kg	50	
☆ QAA19 Zearalenone (LC-MSMS) Method: Food Addit Contam Part A, 2013:30(3),541-9.				
Zearalenone	<25	µg/kg	25	
☆ QD089 Fatty Acids-Omega 6 & 3 %W/W Method: AOCS Ce 2-66 AOCS Ce 1-62				
C08:0 Octanoic (Caprylic)	<0.02	%	0.02	
C10:0 Decanoic (Capric)	<0.02	%	0.02	
C11:0 Undecanoic (Hendecanoic)	<0.02	%	0.02	
C12:0 Dodecanoic (Lauric)	0.13	%	0.02	
C14:0 Tetradecanoic (Myristic)	2.60	%	0.02	
C14:1 Tetradecenoic (Myristoleic)	0.50	%	0.02	
C15:0 Pentadecanoic	1.29	%	0.02	
C15:1 Pentadecenoic	0.02	%	0.02	
C16:0 Hexadecanoic (Palmitic)	34.56	%	0.02	
C16:1 Hexadecenoic (Palmitoleic)	0.27	%	0.02	
C16:2 Hexadecadienoic	<0.02	%	0.02	
C16:3 Hexadecatrienoic	<0.02	%	0.02	
C16:4 Hexadecatetraenoic	<0.02	%	0.02	
C17:0 Heptadecanoic (Margaric)	0.43	%	0.02	
C17:1 Heptadecenoic (Margaroleic)	<0.02	%	0.02	
C18:0 Octadecanoic (Stearic)	1.00	%	0.02	
C18:1 Octadecenoic (Oleic + isomers)	0.44	%	0.02	
C18:2 Octadecadienoic (Linoleic + isomers)	0.85	%	0.02	
C18:2 Octadecadienoic Omega 6 (Linoleic)	0.77	%	0.02	
C18:3 Octadecatrienoic (Linolenic + isomers)	0.19	%	0.02	
C18:3 Octadecatrienoic Omega 3 (Alpha Linolenic)	0.13	%	0.02	
C18:3 Octadecatrienoic Omega 6 (Gamma Linolenic)	0.07	%	0.02	
C18:4 Octadecatetraenoic Omega 3 (Stearidonic)	0.15	%	0.02	
C20:0 Eicosanoic (Arachidic)	0.13	%	0.02	
C20:1 Eicosenoic (Gondoic + isomers)	<0.02	%	0.02	
C20:2 Eicosadienoic Omega 6	<0.02	%	0.02	
C20:3 Eicosatrienoic	0.15	%	0.02	
C20:3 Eicosatrienoic Omega 3	0.06	%	0.02	
C20:3 Eicosatrienoic Omega 6	0.10	%	0.02	
C20:4 Eicosatetraenoic (Arachidonic + isomers)	2.20	%	0.02	
C20:4 Eicosatetraenoic Omega 3	0.48	%	0.02	
C20:4 Eicosatetraenoic Omega 6 (Arachidonic)	1.72	%	0.02	
C20:5 Eicosapentaenoic Omega 3	0.40	%	0.02	
C21:5 Heneicosapentaenoic Omega 3	<0.02	%	0.02	
C22:0 Docosanoic (Behenic)	0.08	%	0.02	
C22:1 Docosenoic (Erucic + isomers)	<0.02	%	0.02	
C22:2 Docosadienoic Omega 6	<0.02	%	0.02	
C22:3 Docosatrienoic, Omega 3	<0.02	%	0.02	
C22:4 Docosatetraenoic Omega 6	0.03	%	0.02	
C22:5 Docosapentaenoic	4.92	%	0.02	
C22:5 Docosapentaenoic Omega 3	0.09	%	0.02	
C22:5 Docosapentaenoic Omega 6	4.83	%	0.02	

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 216000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

	Results	Unit	LOQ	LOD
C22:6 Docosahexaenoic Omega 3	38.06	%	0.02	
C24:0 Tetracosanoic (Lignoceric)	<0.02	%	0.02	
C24:1 Tetracosenoic (Nervonic)	<0.02	%	0.02	
Sum of Omega 3 Isomers	39.37	%	0.06	
Sum of Omega 6 Isomers	7.52	%	0.06	
Total Fat as Triglycerides	92.31	%	0.1	
Total Fatty Acids Calc.	88.42	%	0.1	
Total Monounsaturated Fatty Acids	1.25	%	0.06	
Total Polyunsaturated Fatty Acids	46.96	%	0.06	
Total Saturated Fatty Acids	40.22	%	0.06	
☆ QD163 Moisture by Karl Fischer Method: AOCS Ca 2e-84				
Moisture, Karl Fischer	0.02	%	0.01	
☆ SFFED Pesticide screening using LC/MS/MS in fatty food Selected Parameter(s) Method: § 64 LFGB L 13.04-6 : 2013-08, mod.				
Linuron	<0.01	mg/kg	0.01	
Bromacil	<0.01	mg/kg	0.01	
Pyrethrins	<0.1	mg/kg	0.1	
☆ UMBYM Yeast-Mould E <10 >1500 /g (1) PCCG-P AOAC 997.02 Method: AOAC 997.02				
Moulds	<10	cfu/g		
Yeast	<10	cfu/g		
☆ UMCP8 Salmonella D Abs Pres /25 ml AOAC-RI 121501 Method: AOAC-RI 121501				
Salmonella	Not Detected	/25 ml		
☆ UMM1D Coliforms /ml AOAC 991.14 Method: AOAC 991.14				
Coliforms	<10	cfu/ml		

COMMENT

The content of total plant sterols and plant stanols does not contain cholesterol and non-4-desmethyl sterols (i.e. cycloartenol, 24-methylenecycloartanol, and citrostadienol).

Amount of total GC-eutables is 0,492 mg/100 g.

List of screened molecules (* = limit of quantification)

SUS1A Pesticide Screening(GC) (LOQ* mg/kg)

(a) 2-Phenylphenol (0.01)	(a) Acetochlor (0.05)	(a) Aclonifen (0.05)	(a) Aldrin (0.01)	(a) Ametryne (0.02)	(a) Aramite (0.04)
(a) Atrazine (0.02)	(a) Benfluralin (0.01)	(a) Bifenox (0.05)	(a) Bifenthrin (0.01)	(a) Biphenyl (0.01)	(a) Bromfenvinphos (0.02)
(a) Bromophos (0.01)	(a) Bromophos-ethyl (0.01)	(a) Bromopropylate (0.01)	(a) Butachlor (0.01)	(a) Butafenacil (0.01)	(a) Cadusafos (0.02)
(a) Captafol (0.05)	(a) Captan (0.05)	(a) Captan/THPI (Sum calculated as Captan) ()	(a) Carbophenothion (0.05)	(a) Carbophenothion-methyl (0.05)	(a) Carboxin (0.05)
(a) Chlorbenside (0.05)	(a) Chlordane (Sum) ()	(a) Chlordane, alpha (0.01)	(a) Chlordane, gamma (0.01)	(a) Chlorfenapyr (0.05)	(a) Chlorfenson (0.05)
(a) Chlorfenvinphos (0.01)	(a) Chlormephos (0.05)	(a) Chlorobenzilate (0.01)	(a) Chloroneb (0.01)	(a) Chloropropylate (0.01)	(a) Chlorothalonil (0.01)
(a) Chlorpyrifos (-ethyl) (0.01)	(a) Chlorpyrifos-methyl (0.01)	(a) Chlorthal-dimethyl (0.01)	(a) Chlorthion (0.05)	(a) Chlozolinate (0.02)	(a) Crufomate (0.05)
(a) Cyanazine (0.02)	(a) Cyanofenphos (0.05)	(a) Cyanophos (0.02)	(a) Cyfluthrin (0.05)	(a) Cyhalothrin, lambda-(incl. Cyhalothrin, gamma-) (0.01)	(a) Cypermethrin (0.05)
(a) Cyphenothrin (0.05)	(a) DDD, o,p'- (0.01)	(a) DDD, p,p'- (0.01)	(a) DDE, o,p'- (0.01)	(a) DDE, p,p'- (0.01)	(a) DDT (Sum) ()
(a) DDT, o,p'- (0.01)	(a) DDT, p,p'- (0.01)	(a) Deltamethrin (0.05)	(a) Dichlobenil (0.05)	(a) Dichlofenthion (0.02)	(a) Dichlofluanid (0.02)
(a) Dichlorobenzophenone o,p' (0.02)	(a) Dichlorobenzophenone p,p' (0.02)	(a) Dichlorvos (0.05)	(a) Dicloran (0.05)	(a) Dicofol (Sum) ()	(a) Dicofol, o,p'- (0.02)
(a) Dicofol, p,p'- (0.02)	(a) Dieldrin (0.02)	(a) Dieldrin (Sum) ()	(a) Dienochlor (0.05)	(a) Dinobuton (0.05)	(a) Dioxabenzofos (0.02)
(a) Dioxathion (0.05)	(a) Diphenylamine (0.01)	(a) Edifenphos (0.02)	(a) Endosulfan (Sum) ()	(a) Endosulfan, alpha- (0.05)	(a) Endosulfan, beta- (0.05)
(a) Endosulfan, sulfat- (0.02)	(a) Endrin (0.05)	(a) EPN (0.05)	(a) Ethalfluralin (0.01)	(a) Ethion (0.02)	(a) Etridiazole (0.02)
(a) Etrimfos (0.02)	(a) Fenamiphos (0.05)	(a) Fenchlorphos (0.02)	(a) Fenchlorphos (sum) ()	(a) Fenchlorphos oxon (0.01)	(a) Fenfluthrin (0.01)
(a) Fenitrothion (0.02)	(a) Fenpropathrin (0.02)	(a) Fenson (0.02)	(a) Fenthion (0.02)	(a) Fenvalerate & Esfenvalerate (Sum of RS&SR isomers) (0.02)	(a) Fenvalerate & Esfenvalerate(sum of RR,SS,RS,SR) ()
(a) Fenvalerate & Esfenvalerate(Sum of RR&SS isomers) (0.02)	(a) Fluchloralin (0.05)	(a) Flucythrinate (0.05)	(a) Flumetralin (0.05)	(a) Fluotrimazole (0.01)	(a) Fluquinconazole (0.02)
(a) Fluvalinate-tau (0.02)	(a) Fonofos (0.02)	(a) Formothion (0.05)	(a) HCB (0.01)	(a) HCH gamma(Lindan) (0.01)	(a) HCH, alpha- (0.01)
(a) HCH, beta- (0.01)	(a) HCH, delta- (0.01)	(a) HCH, epsilon- (0.01)	(a) Heptachlor (0.01)	(a) Heptachlor (Sum) ()	(a) Heptachlor epoxide cis (0.01)
(a) Heptachlor epoxide trans (0.01)	(a) Heptenophos (0.02)	(a) Iprobenfos (0.02)	(a) Isazofos (0.01)	(a) Isocarbophos (0.02)	(a) Isodrin (0.02)
(a) Isofenphos (0.02)	(a) Isofenphos-methyl (0.01)	(a) Isoprothiolane (0.02)	(a) Jodfenphos (0.02)	(a) Kresoxim-methyl (0.01)	(a) Landrin (0.02)
(a) Malaoxon (0.05)	(a) Malathion (0.02)	(a) Malathion (Sum) ()	(a) Mecarbam (0.04)	(a) Mepronil (0.01)	(a) Methacrifos (0.02)
(a) Methamidophos (0.1)	(a) Methidathion (0.02)	(a) Methoxychlor (0.02)	(a) Methyl-Pentachlorophenylsulfide (0.05)	(a) Metribuzin (0.04)	(a) Mevinphos (0.02)
(a) Mirex (0.01)	(a) N-Desethyl-pirimiphos-methyl (0.01)	(a) Nitrapyrin (0.01)	(a) Nitrofen (0.02)	(a) Nitrothal-isopropyl (0.01)	(a) Octachlorodipropyl ether (S-421) (0.05)
(a) Ofurace (0.01)	(a) Oxadiazon (0.02)	(a) Oxychlordane (0.02)	(a) Oxyfluorfen (0.02)	(a) Paclobutrazol (0.01)	(a) Parathion (0.04)
(a) Parathion-methyl (0.04)	(a) PCB 101 (0.01)	(a) PCB 118 (0.01)	(a) PCB 138 (0.01)	(a) PCB 153 (0.01)	(a) PCB 180 (0.01)
(a) PCB 28 (0.01)	(a) PCB 52 (0.01)	(a) Pentachloroaniline (0.01)	(a) Pentachloroanisole (0.01)	(a) Pentachlorobenzene (0.01)	(a) Permethrin (0.02)
(a) Phenkapton (0.05)	(a) Phenothrin (0.01)	(a) Phenthoate (0.02)	(a) Phorate (0.04)	(a) Phosphamidon (0.04)	(a) Picoxystrobin (0.01)
(a) Piperophos (0.01)	(a) Pirimiphos-ethyl (0.01)	(a) Procymidone (0.01)	(a) Profenofos (0.01)	(a) Profluralin (0.02)	(a) Prometryn (0.02)
(a) Propanil (0.01)	(a) Propazine (0.01)	(a) Prothiofos (0.02)	(a) Pyrazophos (0.01)	(a) Pyridalyl (0.05)	(a) Pyridaphenthion (0.02)
(a) Pyrifenox (0.04)	(a) Pyrimethanil (0.01)	(a) Quinalphos (0.01)	(a) Quintozene (0.01)	(a) Quizalofop-P-ethyl (0.01)	(a) Silafluofen (0.05)

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

(a) Silthiofam (0.01)	(a) Tebufenpyrad (0.01)	(a) Teclazavre (0.02)	(a) Tefluthrin (0.02)	(a) Terbufos (0.02)	(a) Tetrachlorvinphos (0.02)
(a) Tebuconazole (0.02)	(a) Tetrahydrophthalimide (THPI) (0.05)	(a) Tetramethrin (0.02)	(a) Tetrasul (0.01)	(a) Tolylfluanid (0.02)	(a) Triallate (0.02)
(a) Triazamate (0.01)	(a) Trichlorfon (0.02)	(a) Trichlorfonal (0.01)	(a) Trifloxystrobin (0.02)	(a) Triticonazole (0.01)	(a) Uniconazole (0.02)
(a) Vinclozolin (0.02)					

SIGNATURE

Claire Wang
Authorized Signatory

Shine Xie
Authorized Signatory

EXPLANATORY NOTE

LOQ: Limit of Quantification
< LOQ: Below Limit of Quantification
N/A means Not applicable
+ CNAS # DAKKS =CMA
☆ means the test is subcontracted within Eurofins group
° means the test is subcontracted outside Eurofins group

Sum compounds results are calculated from the results of each quantified compound as set by regulation
The result(s) relate(s) only to the item(s) tested and is(are) only for internal use by the client and not for publicly available as evidence.
This analytical report shall not be reproduced except in full, without written approval of the laboratory.
Eurofins General Terms and Conditions apply.
For and on behalf of Eurofins Technology Service (Suzhou) Co., Ltd

END OF REPORT

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 826 5088
Fax
www.eurofins.cn

eurofins

Certificate No.: PR-19-SU-000051-01

Physical inspection

Sample code	502-2019-00010197
Sample name	DHA oil
Color	Light yellow
Odor	Have the special odor of this product
Texture	Oily liquid

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax +86 512 6878 5966
www.eurofins.cn

eurofins

Preliminary report

Analytical Report

Sample Code	502-2019-00010195	Report date	25-Mar-2019
Certificate No.	PR-19-SU-000049-01		

HuBei Fuxing Biotechnology CO,.LTD
Yanrong Wu
NO.18 Fuxing Street, Chenhu Town,
Hanchuan, Hubei, P.R. China
Fax 0086 0712-8741957

Our reference:	502-2019-00010195/ PR-19-SU-000049-01
Client Sample Code:	D18111401J
Sample described as:	DHA油脂
Sample Packaging:	Sealed metal bottle
Sample reception date:	20-Feb-2019
Analysis starting date:	20-Feb-2019
Analysis ending date:	22-Mar-2019
Arrival Temperature (°C)	17.6
Sample Weight	600g*2

		Results	Unit	LOQ	LOD
SU007	Mercury (AAS) Method: BS EN 13806:2002				
	Mercury (Hg)	<0.005	mg/kg	0.005	
SU051	Manganese (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Manganese (Mn)	<0.1	mg/kg	0.1	
SU056	Molybdenum (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Molybdenum (Mo)	<0.03	mg/kg	0.03	
SU056	Nickel (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Nickel (Ni)	<0.1	mg/kg	0.1	
SU05D	Lead (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Lead (Pb)	<0.05	mg/kg	0.05	
SU05E	Arsenic (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Arsenic (As)	<0.05	mg/kg	0.05	
SU05F	Chromium (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Chromium (Cr)	<0.1	mg/kg	0.1	
SU05G	Cadmium (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Cadmium (Cd)	<0.01	mg/kg	0.01	
SU05J	Copper (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Copper (Cu)	<0.1	mg/kg	0.1	
SU05K	Phosphorus (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Phosphorus (P)	44.6	mg/kg	5	
SU61B	Iron (ICP-OES) Method: Internal Method ICP-OES, ICP-OES				
	Iron (Fe)	<0.1	mg/100 g	0.1	

		Results	Unit	LOQ	LOD
SUS1A	Pesticide Screening(GC) Method: BS EN 12393:2013				
	Screened pesticides	<LOQ	mg/kg		

		Results	Unit	LOQ	LOD
SU10Z	Cronobacter spp. in 10g Method: ISO 22964:2017				
	Cronobacter spp	Not Detected	/10 g		

		Results	Unit	LOQ	LOD
SU20L	Protein Method: AOAC 984.13				

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 216000
Jiangsu Province, P.R. China
Phone +86 400 826 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

		Results	Unit	LOQ	LOD
	Protein	<0.1 (k=6.25)	g/100 g	0.1	
SU217	Physical inspection Method: Internal Method, Organoleptic evaluation				
	Physical inspection	see attached document			
SU227	Ash Method: AOAC 941.12; AOAC 923.03				
	Ash	0.03	g/100 g	0.01	
SU372	Cholesterol Method: GB 5009.128-2016				
	Cholesterol	2305	mg/kg	10	

		Results	Unit	LOQ	LOD
☆ SF0XA	add 1 on to the GC/MS-pesticide screening Selected Parameter(s) Method: § 64 LFGB L 00.00-34 : 2010-09, mod.				
	Tralomethrin	<0.05	mg/kg	0.05	
☆ FL023	Plant sterols and plant stanols (not enriched) Method: NMKL 198:2014				
	Brassicasterol	15	mg/100 g	1	
	Cholesterol	210	mg/100 g	1	
	Campesterol	15	mg/100 g	1	
	Campestanol	1	mg/100 g	1	
	Stigmasterol	28	mg/100 g	1	
	Unidentified sterols	197	mg/100 g	1	
	Sitosterol	68	mg/100 g	1	
	Sitostanol+ delta-5-avenasterol	8	mg/100 g	1	
	Delta-5,24-stigmastadienol	10	mg/100 g	1	
	Delta-7-stigmastenol	28	mg/100 g	1	
	delta-7-Avenasterol	6	mg/100 g	1	
	Cycloartenol	3	mg/100 g	1	
	24-Methylenecycloartanol	3	mg/100 g	1	
	Citrostadienol	2	mg/100 g	1	
	Total plant sterols + plant stanols	375	mg/100 g	1	
☆ JC00V	PAH acc. to EU 208/2006 (15+1) Method: Internal, GC-MS				
	5-Methylchrysene	<1	µg/kg	1	
	Benz(a)anthracene	<0.5	µg/kg	0.5	
	Benzo(a)pyrene	<0.5	µg/kg	0.5	
	Benzo(b)fluoranthene	<0.5	µg/kg	0.5	
	Benzo-(c)-fluorene	<1	µg/kg	1	
	Benzo(g,h,i)perylene	<0.5	µg/kg	0.5	
	Benzo-(j)-fluoranthen	<0.5	µg/kg	0.5	
	Benzo(k)fluoranthene	<0.5	µg/kg	0.5	
	Chrysene	<0.5	µg/kg	0.5	
	Cyclopenta(c,d)pyrene	<1	µg/kg	1	
	Dibenz(a,h)anthracene	<0.5	µg/kg	0.5	
	Dibenzo(a,e)pyrene	<1	µg/kg	1	
	Dibenzo(a,h)pyrene	<1	µg/kg	1	
	Dibenzo(a,i)pyrene	<1	µg/kg	1	
	Dibenzo(a,l)pyrene	<1	µg/kg	1	
	Indeno(1,2,3-cd)pyrene	<0.5	µg/kg	0.5	
	Sum of all positive identified PAH	Inapplicable	µg/kg		
	Sum PAH 4	Inapplicable	µg/kg		
☆ JC0A9	Patulin (oil) Method: Internal, LC-MS/MS				
	Patulin	<5	µg/kg	5	
☆ JCAF2	Aflatoxins B1, B2, G1, G2 (fats, oils, lecithin, egg powder) Method: internal method based on EN 14123				
	Aflatoxin B1	<0.1	µg/kg	0.1	
	Aflatoxin B2	<0.1	µg/kg	0.1	
	Aflatoxin G1	<0.1	µg/kg	0.1	
	Aflatoxin G2	<0.1	µg/kg	0.1	

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 216000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

	Results	Unit	LOQ	LOD
Sum of all positive Aflatoxins	<0.4	µg/kg		
☆ JJW2Z Sterigmatocystin Method: Internal, LC-MS/MS				
Sterigmatocystin	<10	µg/kg	10	
☆ LW0XD Domoic acid, DA Method: In house method (210), LC-MS				
Amnesic Shellfish Poison, Domoic Acid	Not Detected			
Amnesic Shellfish Poison, Domoic acid	<3.0	µg/g	3	
☆ QA00F Peroxide Value Method: AOCS Cd 8-53				
Peroxide value	<0.1	meq/kg	0.1	
☆ QA00I Acid Value Method: AOCS Cd 3d-63				
Acid value (mg KOH/g)	0.38	mg KOH/g	0.05	
Free fatty acids (as oleic acid)	0.19	%	0.01	
☆ QA01L p-Anisidine Value Method: AOCS Cd 18-90				
p-Anisidine Value	5.7		1	
☆ QA02L Color (Lovibond Scale) Method: AOCS Cc 13e-92; ISO 15305				
Color, red scale, 1 inch cell path	0.9			
Color, yellow scale, 1 inch cell path	9			
☆ QA034 Fumonisins (IAC-LC-MSMS) Method: JAOAC, 92 (2), 496.				
Fumonisin (B1+B2+B3)	<30	µg/kg	30	
Fumonisin B1	<10	µg/kg	10	
Fumonisin B2	<10	µg/kg	10	
Fumonisin B3	<10	µg/kg	10	
☆ QA04E Residual Solvents (GC-MS) Method: AOCS Cg 4-94				
1,1,1-Trichloroethane	<0.2	mg/kg	0.2	
1,1,2-Trichloroethane	<0.2	mg/kg	0.2	
1,2-Dichloroethane	<0.5	mg/kg	0.5	
1,2-Dimethoxyethane	<1	mg/kg	1	
1-Butanol	<1	mg/kg	1	
2-Hexanone	<1	mg/kg	1	
Acetone	<1	mg/kg	1	
Benzene	<0.1	mg/kg	0.1	
Butyl acetate	<0.5	mg/kg	0.5	
Carbon tetrachloride	<0.5	mg/kg	0.5	
Chlorobenzene	<0.5	mg/kg	0.5	
Chloroform	<0.1	mg/kg	0.1	
Cyclohexane	<0.2	mg/kg	0.2	
Dichloromethane	<0.1	mg/kg	0.1	
Ethanol	<1	mg/kg	1	
Ethyl acetate	<1	mg/kg	1	
Heptane	<0.2	mg/kg	0.2	
Hexane (sum of n-hexane, iso and 3-methyl pentane)	<0.5	mg/kg	0.5	
Isopropanol	<1	mg/kg	1	
Methanol	<1	mg/kg	1	
Methyl Ethyl Ketone (MEK)	<0.2	mg/kg	0.2	
Methyl-tert-butylether (MTBE)	<0.2	mg/kg	0.2	
Tetralin	<5	mg/kg	5	
Toluene	<0.2	mg/kg	0.2	
Trichloroethylene	<0.1	mg/kg	0.1	
Xylenes (sum)	<0.2	mg/kg	0.2	
☆ QA062 Polychlorinated Biphenyls (Oils & Fats) Method: ASU L00.00-34				
PCB 1	<0.01	mg/kg	0.01	
PCB 101	<0.01	mg/kg	0.01	
PCB 104	<0.01	mg/kg	0.01	
PCB 105	<0.01	mg/kg	0.01	

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

	Results	Unit	LOQ	LOD
PCB 118	<0.01	mg/kg	0.01	
PCB 126	<0.01	mg/kg	0.01	
PCB 128	<0.01	mg/kg	0.01	
PCB 138	<0.01	mg/kg	0.01	
PCB 153	<0.01	mg/kg	0.01	
PCB 170	<0.01	mg/kg	0.01	
PCB 18	<0.01	mg/kg	0.01	
PCB 180	<0.01	mg/kg	0.01	
PCB 187	<0.01	mg/kg	0.01	
PCB 188	<0.01	mg/kg	0.01	
PCB 195	<0.01	mg/kg	0.01	
PCB 201	<0.01	mg/kg	0.01	
PCB 206	<0.01	mg/kg	0.01	
PCB 209	<0.01	mg/kg	0.01	
PCB 28	<0.01	mg/kg	0.01	
PCB 29	<0.01	mg/kg	0.01	
PCB 44	<0.01	mg/kg	0.01	
PCB 50	<0.01	mg/kg	0.01	
PCB 52	<0.01	mg/kg	0.01	
PCB 66	<0.01	mg/kg	0.01	
PCB 77	<0.01	mg/kg	0.01	
PCB 8	<0.01	mg/kg	0.01	
PCB 87	<0.01	mg/kg	0.01	
Sum Non-Dioxin-Like PCBs (28+52+101+138+153+180)	<0.01	mg/kg	0.01	
Total PCB	<0.1	mg/kg	0.1	
☆ QA0MT Ochratoxin A (HPLC-FLD) Method: AOAC 2000.16				
Ochratoxin A	<1	µg/kg	1	
☆ QA23L Trans Fatty Acids, relative area % (GC-FID) Method: AOCS Ce 1f-96				
Total Trans Fatty Acids	0.15	% of fatty acids	0.01	
total trans fatty acids C18:1	<0.01	% of fatty acids	0.01	
total trans fatty acids C18:2 (without CLA)	0.15	% of fatty acids	0.01	
total trans fatty acids C18:2 + C18:3	0.15	% of fatty acids	0.01	
total trans fatty acids C18:3	<0.01	% of fatty acids	0.01	
☆ QA282 Free Fatty Acid, as Oleic Method: AOCS Ca 5a-40				
Free fatty acids as oleic acid	0.20	%	0.01	
☆ QA328 Insoluble Impurities Method: AOCS Ca 3a-46				
Insoluble impurities	<0.01	%	0.01	
☆ QA513 Toxaphene (GC-MSMS)				
Toxaphene Parlar 26	<LOQ	mg/kg	0.01	
Toxaphene Parlar 50	<LOQ	mg/kg	0.01	
Toxaphene Parlar 62	not analyzable	mg/kg	0.01	
☆ QA560 Sulfallate (Vegedex)				
Sulfallate (Vegedex)	<0.02	mg/kg	0.02	
☆ QA867 Silicon (ICP-AES) Method: AOCS Ca 17-01				
Silicon (Si)	3.9	mg/kg	1	
☆ QA967 Unsaponifiable Matter (Ethyl ether ext) Method: AOCS Ca 6b-53				
Unsaponifiable matter	1.58	%	0.05	
☆ QAA07 Vomitoxin (Deoxynivalenol, DON) LC-MSMS Method: Food Addit Contam Part A, 2013:30(3),541-9.				

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China
Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

	Results	Unit	LOQ	LOD
Vomitoxin (Deoxynivalenol)	<50	µg/kg	50	
☆ QAA19 Zearalenone (LC-MSMS) Method: Food Addit Contam Part A, 2013:30(3),641-9.				
Zearalenone	<25	µg/kg	25	
☆ QD089 Fatty Acids-Omega 6 & 3 %W/W Method: AOCS Ce 2-66 AOCS Ce 1-62				
C08:0 Octanoic (Caprylic)	<0.02	%	0.02	
C10:0 Decanoic (Capric)	<0.02	%	0.02	
C11:0 Undecanoic (Hendecanoic)	<0.02	%	0.02	
C12:0 Dodecanoic (Lauric)	0.04	%	0.02	
C14:0 Tetradecanoic (Myristic)	0.46	%	0.02	
C14:1 Tetradecenoic (Myristoleic)	<0.02	%	0.02	
C15:0 Pentadecanoic	0.80	%	0.02	
C15:1 Pentadecenoic	<0.02	%	0.02	
C16:0 Hexadecanoic (Palmitic)	22.30	%	0.02	
C16:1 Hexadecenoic (Palmitoleic)	0.13	%	0.02	
C16:2 Hexadecadienoic	<0.02	%	0.02	
C16:3 Hexadecatrienoic	<0.02	%	0.02	
C16:4 Hexadecatetraenoic	<0.02	%	0.02	
C17:0 Heptadecanoic (Margaric)	0.99	%	0.02	
C17:1 Heptadecenoic (Margaroleic)	0.02	%	0.02	
C18:0 Octadecanoic (Stearic)	1.25	%	0.02	
C18:1 Octadecenoic (Oleic + isomers)	3.29	%	0.02	
C18:2 Octadecadienoic (Linoleic + isomers)	6.99	%	0.02	
C18:2 Octadecadienoic Omega 6 (Linoleic)	6.88	%	0.02	
C18:3 Octadecatrienoic (Linolenic + isomers)	0.91	%	0.02	
C18:3 Octadecatrienoic Omega 3 (Alpha Linolenic)	0.76	%	0.02	
C18:3 Octadecatrienoic Omega 6 (Gamma Linolenic)	0.15	%	0.02	
C18:4 Octadecatetraenoic Omega 3 (Stearidonic)	0.11	%	0.02	
C20:0 Eicosanoic (Arachidic)	0.27	%	0.02	
C20:1 Eicosenoic (Gondoic + isomers)	0.06	%	0.02	
C20:2 Eicosadienoic Omega 6	0.04	%	0.02	
C20:3 Eicosatrienoic	0.23	%	0.02	
C20:3 Eicosatrienoic Omega 3	<0.02	%	0.02	
C20:3 Eicosatrienoic Omega 6	0.23	%	0.02	
C20:4 Eicosatetraenoic (Arachidonic + isomers)	1.09	%	0.02	
C20:4 Eicosatetraenoic Omega 3	0.50	%	0.02	
C20:4 Eicosatetraenoic Omega 6 (Arachidonic)	0.59	%	0.02	
C20:5 Eicosapentaenoic Omega 3	0.23	%	0.02	
C21:5 Heneicosapentaenoic Omega 3	<0.02	%	0.02	
C22:0 Docosanoic (Behenic)	0.16	%	0.02	
C22:1 Docosenoic (Erucic + isomers)	<0.02	%	0.02	
C22:2 Docosadienoic Omega 6	<0.02	%	0.02	
C22:3 Docosatrienoic, Omega 3	<0.02	%	0.02	
C22:4 Docosatetraenoic Omega 6	0.06	%	0.02	
C22:5 Docosapentaenoic	10.96	%	0.02	
C22:5 Docosapentaenoic Omega 3	0.06	%	0.02	
C22:5 Docosapentaenoic Omega 6	10.90	%	0.02	

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 216000
Jiangsu Province, P.R. China

Phone +86 400 826 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

	Results	Unit	LOQ	LOD
C22:6 Docosahexaenoic Omega 3	38.78	%	0.02	
C24:0 Tetracosanoic (Lignoceric)	0.15	%	0.02	
C24:1 Tetracosenoic (Nervonic)	<0.02	%	0.02	
Sum of Omega 3 Isomers	40.45	%	0.05	
Sum of Omega 6 Isomers	18.85	%	0.05	
Total Fat as Triglycerides	93.15	%	0.1	
Total Fatty Acids Calc.	89.35	%	0.1	
Total Monounsaturated Fatty Acids	3.50	%	0.05	
Total Polyunsaturated Fatty Acids	59.40	%	0.05	
Total Saturated Fatty Acids	26.44	%	0.05	
☆ QD153 Moisture by Karl Fischer Method: AOCS Ca 2e-84				
Moisture, Karl Fischer	0.02	%	0.01	
☆ SFFED Pesticide screening using LC/MS/MS in fatty food Selected Parameter(s) Method: § 64 LFGB L 13.04-6 : 2013-08, mod.				
Linuron	<0.01	mg/kg	0.01	
Bromacil	<0.01	mg/kg	0.01	
Pyrethrins	<0.1	mg/kg	0.1	
☆ UMBYM Yeast-Mould E <10 >1500 /g (1) PCCG-P AOAC 997.02 Method: AOAC 997.02				
Moulds	<10	cfu/g		
Yeast	<10	cfu/g		
☆ UMCP8 Salmonella D Abs Pres /25 ml AOAC-RI 121501 Method: AOAC-RI 121501				
Salmonella	Not Detected	/25 ml		
☆ UMM1D Coliforms /ml AOAC 991.14 Method: AOAC 991.14				
Coliforms	<10	cfu/ml		

COMMENT

The content of total plant sterols and plant stanols does not contain cholesterol and non-4-desmethyl sterols (i.e. cycloartenol, 24-methylenecycloartanol, and citrostadienol).

Amount of total GC-eutables is 0,875 mg/100 g.

List of screened molecules (* = limit of quantification)

SUS1A Pesticide Screening(GC) (LOQ* mg/kg)

(a) 2-Phenylphenol (0.01)	(a) Acebochlor (0.05)	(a) Acrinathrin (0.05)	(a) Aldrin (0.01)	(a) Ametryne (0.02)	(a) Azoxide (0.04)
(a) Abscisine (0.02)	(a) Benfluralin (0.01)	(a) Bifenox (0.05)	(a) Bifenthrin (0.01)	(a) Biphenyl (0.01)	(a) Bromfenvinfos (0.02)
(a) Bromophos (0.01)	(a) Bromophos-ethyl (0.01)	(a) Bromopropylate (0.01)	(a) Butachlor (0.01)	(a) Butafenacil (0.01)	(a) Cadusafos (0.02)
(a) Captafol (0.06)	(a) Captan (0.06)	(a) Captan/THPI (Sum calculated as Captan) ()	(a) Carbophenothion (0.05)	(a) Carbophenothion-methyl (0.05)	(a) Carbofuran (0.05)
(a) Chlorbenside (0.05)	(a) Chlordane (Sum) ()	(a) Chlordane, alpha (0.01)	(a) Chlordane, gamma (0.01)	(a) Chlorfenapyr (0.05)	(a) Chlorfenson (0.05)
(a) Chlorfenvinphos (0.01)	(a) Chlormephos (0.05)	(a) Chlorobenzilate (0.01)	(a) Chloroneb (0.01)	(a) Chloropropylate (0.01)	(a) Chlorothalonil (0.01)
(a) Chlorpyrifos (-ethyl) (0.01)	(a) Chlorpyrifos-methyl (0.01)	(a) Chlorthal-dimethyl (0.01)	(a) Chlorthion (0.05)	(a) Chlozolinate (0.02)	(a) Cinfonazole (0.05)
(a) Cyanazine (0.02)	(a) Cyanofenphos (0.05)	(a) Cyanophos (0.02)	(a) Cyfluthrin (0.05)	(a) Cyhalothrin, lambda-(incl. Cyhalothrin, gamma-) (0.01)	(a) Cypermethrin (0.05)
(a) Cyphenothrin (0.05)	(a) DDD, o,p'- (0.01)	(a) DDD, p,p'- (0.01)	(a) DDE, o,p'- (0.01)	(a) DDE, o,p'- (0.01)	(a) DDT (Sum) ()
(a) DDT, o,p'- (0.01)	(a) DDT, p,p'- (0.01)	(a) Deltamethrin (0.05)	(a) Dichlobenil (0.05)	(a) Dichlofenthion (0.02)	(a) Dichlofluanid (0.02)
(a) Dichlorobenzophenone o,p' (0.02)	(a) Dichlorobenzophenone p,p' (0.02)	(a) Dichlorvos (0.05)	(a) Diclofop (Sum) ()	(a) Diclofol (Sum) ()	(a) Diclofol, o,p'- (0.02)
(a) Diclofol, p,p'- (0.02)	(a) Dieldrin (0.02)	(a) Dieldrin (Sum) ()	(a) Dienochlor (0.05)	(a) Dinobuton (0.05)	(a) Dioxabenzofos (0.02)
(a) Dioxathion (0.05)	(a) Diphenylamine (0.01)	(a) Edifenphos (0.02)	(a) Endosulfan (Sum) ()	(a) Endosulfan, alpha- (0.05)	(a) Endosulfan, beta- (0.05)
(a) Endosulfan, sulfat- (0.02)	(a) Endrin (0.05)	(a) EPN (0.05)	(a) Ethalfluralin (0.01)	(a) Ethion (0.02)	(a) Etridiazole (0.02)
(a) Etrimfos (0.02)	(a) Fenamiphos (0.05)	(a) Fenchlorphos (0.02)	(a) Fenchlorphos (sum) ()	(a) Fenchlorphos oxon (0.01)	(a) Fenfluthrin (0.01)
(a) Fenitrothion (0.02)	(a) Fenpropathrin (0.02)	(a) Fenson (0.02)	(a) Fenthion (0.02)	(a) Fenvalerate & Esfenvalerate (Sum of RSR&SR isomers) (0.02)	(a) Fenvalerate & Esfenvalerate(sum of RR,SS,RS,SR) ()
(a) Fenvalerate & Esfenvalerate(Sum of RR&SS isomers) (0.02)	(a) Flucitrinate (0.05)	(a) Flucythrinate (0.05)	(a) Flumetralin (0.05)	(a) Fluotrimazole (0.01)	(a) Fluquinconazole (0.02)
(a) Fluvalinate-tau (0.02)	(a) Fonofos (0.02)	(a) Formothion (0.05)	(a) HCB (0.01)	(a) HCH gamma(Lindan) (0.01)	(a) HCH, alpha- (0.01)
(a) HCH, beta- (0.01)	(a) HCH, delta- (0.01)	(a) HCH, epsilon- (0.01)	(a) Heptachlor (0.01)	(a) Heptachlor (Sum) ()	(a) Heptachlor epoxide cis (0.01)
(a) Heptachlor epoxide trans (0.01)	(a) Heptenophos (0.02)	(a) Iprobenfos (0.02)	(a) Isazofos (0.01)	(a) Isocarbophos (0.02)	(a) Isodrin (0.02)
(a) Isofenphos (0.02)	(a) Isofenphos-methyl (0.01)	(a) Isoprothiolane (0.02)	(a) Jodfenphos (0.02)	(a) Kresoxim-methyl (0.01)	(a) Lindrin (0.02)
(a) Malaoxon (0.05)	(a) Malathion (0.02)	(a) Malathion (Sum) ()	(a) Mecarbam (0.04)	(a) Mepronil (0.01)	(a) Methacrifos (0.02)
(a) Methamidophos (0.1)	(a) Methidathion (0.02)	(a) Methoxychlor (0.02)	(a) Methyl-Pentachlorophenylsulfide (0.05)	(a) Metribuzin (0.04)	(a) Mevinphos (0.02)
(a) Mirex (0.01)	(a) N-Desethyl-pirimiphos-methyl (0.01)	(a) Nitrapyrin (0.01)	(a) Nitrofen (0.02)	(a) Nitrothal-isopropyl (0.01)	(a) Octachlorodipropyl ether (S-421) (0.05)
(a) Ofurace (0.01)	(a) Oxadixon (0.02)	(a) Oxychlordane (0.02)	(a) Oxyfluorfen (0.02)	(a) Paclobutrazol (0.01)	(a) Parathion (0.01)
(a) Parathion-methyl (0.04)	(a) PCB 101 (0.01)	(a) PCB 110 (0.01)	(a) PCB 138 (0.01)	(a) PCB 153 (0.01)	(a) PCB 180 (0.01)
(a) PCB 28 (0.01)	(a) PCB 52 (0.01)	(a) Pentachloroaniline (0.01)	(a) Pentachlorobenzamide (0.01)	(a) Pentachloronitrobenzene (0.01)	(a) Permethrin (0.02)
(a) Phenkapton (0.05)	(a) Phenothrin (0.01)	(a) Phenthoate (0.02)	(a) Phorate (0.04)	(a) Phosphamidon (0.04)	(a) Picoxystrobin (0.01)
(a) Piperophos (0.01)	(a) Pirimiphos-ethyl (0.01)	(a) Procymidone (0.01)	(a) Profenofos (0.01)	(a) Profluralin (0.02)	(a) Prometryn (0.02)
(a) Propanil (0.01)	(a) Propazine (0.01)	(a) Prothiofos (0.02)	(a) Pyrazophos (0.01)	(a) Pyridalyl (0.06)	(a) Pyridaphenthion (0.02)
(a) Pyrifenox (0.04)	(a) Pyrimethanil (0.01)	(a) Quinalphos (0.01)	(a) Quinoxyfen (0.01)	(a) Quizalofop-P-ethyl (0.01)	(a) Silafluofen (0.06)

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

(a) Silthiofam (0.01)	(a) Tebufenpyrad (0.01)	(a) Tecnazene (0.02)	(a) Teflubenzuron (0.02)	(a) Tetradifon (0.02)	(a) Tetrachlorvinphos (0.02)
(a) Tetraconazole (0.02)	(a) Tetrahydrophthalimide (THPI) (0.06)	(a) Tetramethrin (0.02)	(a) Tetramisol (0.01)	(a) Tolylfluanid (0.02)	(a) Triadimefon (0.02)
(a) Triazamate (0.01)	(a) Triazophos (0.02)	(a) Trichloronat (0.01)	(a) Triflumizole (0.02)	(a) Triticonazole (0.01)	(a) Uniconazole (0.02)
(a) Vinclozolin (0.02)					

SIGNATURE

Claire Wang
Authorized Signatory

Shine Xie
Authorized Signatory

EXPLANATORY NOTE

LOQ: Limit of Quantification
< LOQ: Below Limit of Quantification
N/A means Not applicable
+ CNAS # DAKKS ^CMA
☆ means the test is subcontracted within Eurofins group
° means the test is subcontracted outside Eurofins group

Sum compounds results are calculated from the results of each quantified compound as set by regulation
The result(s) relate(s) only to the item(s) tested and is(are) only for internal use by the client and not for publicly available as evidence.
This analytical report shall not be reproduced except in full, without written approval of the laboratory.
Eurofins General Terms and Conditions apply.
For and on behalf of Eurofins Technology Service (Suzhou) Co., Ltd

END OF REPORT

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 216000
Jiangsu Province, P.R. China

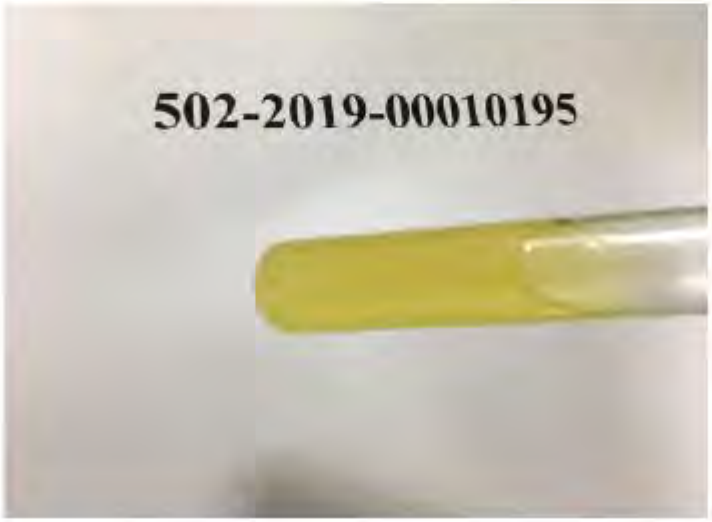
Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Certificate No.: PR-19-SU-000049-01

Physical inspection

Sample code	502-2019-00010195
Sample name	DHA oil
Color	Light yellow
Odor	Have the special odor of this product
Texture	Oily liquid



Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax +86 512 6878 5966
www.eurofins.cn

eurofins

Preliminary report

Analytical Report

Sample Code	502-2019-00010194	Report date	25-Mar-2019
Certificate No.	PR-19-SU-000048-01		

HuBei Fuxing Biotechnology CO,.LTD
Yanrong Wu
NO.18 Fuxing Street, Chenhu Town,
Hanchuan, Hubei, P.R. China
Fax 0086 0712-8741957

Our reference:	502-2019-00010194/ PR-19-SU-000048-01
Client Sample Code:	D18122601J
Sample described as:	DHA油脂
Sample Packaging:	Sealed metal bottle
Sample reception date:	20-Feb-2019
Analysis starting date:	20-Feb-2019
Analysis ending date:	22-Mar-2019
Arrival Temperature (°C)	17.6
Sample Weight	600g*2

		Results	Unit	LOQ	LOD
SU007	Mercury (AAS) Method: BS EN 13806:2002				
	Mercury (Hg)	<0.005	mg/kg	0.005	
SU061	Manganese (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Manganese (Mn)	<0.1	mg/kg	0.1	
SU065	Molybdenum (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Molybdenum (Mo)	<0.03	mg/kg	0.03	
SU066	Nickel (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Nickel (Ni)	<0.1	mg/kg	0.1	
SU06D	Lead (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Lead (Pb)	<0.05	mg/kg	0.05	
SU06E	Arsenic (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Arsenic (As)	<0.05	mg/kg	0.05	
SU06F	Chromium (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Chromium (Cr)	<0.1	mg/kg	0.1	
SU06G	Cadmium (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Cadmium (Cd)	<0.01	mg/kg	0.01	
SU06J	Copper (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Copper (Cu)	<0.1	mg/kg	0.1	
SU06K	Phosphorus (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Phosphorus (P)	39.3	mg/kg	5	
SU51B	Iron (ICP-OES) Method: Internal Method ICP-OES, ICP-OES				
	Iron (Fe)	<0.1	mg/100 g	0.1	

		Results	Unit	LOQ	LOD
SUS1A	Pesticide Screening(GC) Method: BS EN 12393:2013				
	Screened pesticides	<LOQ	mg/kg		

		Results	Unit	LOQ	LOD
SU10Z	Cronobacter spp. in 10g Method: ISO 22964:2017				
	Cronobacter spp	Not Detected	/10 g		

		Results	Unit	LOQ	LOD
SU20L	Protein Method: AOAC 984.13				

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China
Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

		Results	Unit	LOQ	LOD
	Protein	<0.1 (k=6.25)	g/100 g	0.1	
SU217	Physical inspection Method: Internal Method, Organoleptic evaluation				
	Physical inspection	see attached document			
SU227	Ash Method: AOAC 941.12; AOAC 923.03				
	Ash	0.05	g/100 g	0.01	
SU372	Cholesterol Method: GB 5009.128-2016				
	Cholesterol	1200	mg/kg	10	

		Results	Unit	LOQ	LOD
☆ SF0XA	add 1 on to the GC/MS-pesticide screening Selected Parameter(s) Method: § 64 LFGB L 00.00-34 : 2010-09, mod.				
	Tralomethrin	<0.05	mg/kg	0.05	
☆ FL023	Plant sterols and plant stanols (not enriched) Method: NMKL 198:2014				
	Brassicasterol	10	mg/100 g	1	
	Cholesterol	114	mg/100 g	1	
	Campesterol	5	mg/100 g	1	
	Campestanol	1	mg/100 g	1	
	Stigmasterol	10	mg/100 g	1	
	Unidentified sterols	116	mg/100 g	1	
	Sitosterol	23	mg/100 g	1	
	Sitostanol+ delta-5-avenasterol	6	mg/100 g	1	
	Delta-5,24-stigmastadienol	3	mg/100 g	1	
	Delta-7-stigmastenol	13	mg/100 g	1	
	delta-7-Avenasterol	1	mg/100 g	1	
	Cycloartenol	2	mg/100 g	1	
	24-Methylenecycloartanol	3	mg/100 g	1	
	Citrostadienol	1	mg/100 g	1	
	Total plant sterols + plant stanols	188	mg/100 g	1	
☆ JC00V	PAH acc. to EU 208/2005 (16+1) Method: Internal, GC-MS				
	5-Methylchrysene	<1	µg/kg	1	
	Benz(a)anthracene	<0.5	µg/kg	0.5	
	Benzo(a)pyrene	<0.5	µg/kg	0.5	
	Benzo(b)fluoranthene	<0.5	µg/kg	0.5	
	Benzo-(c)-fluorene	<1	µg/kg	1	
	Benzo(g,h,i)perylene	<0.5	µg/kg	0.5	
	Benzo-(j)-fluoranthen	0.6	µg/kg	0.5	
	Benzo(k)fluoranthene	<0.5	µg/kg	0.5	
	Chrysene	<0.5	µg/kg	0.5	
	Cyclopenta(c,d)pyrene	<1	µg/kg	1	
	Dibenz(a,h)anthracene	<0.5	µg/kg	0.5	
	Dibenzo(a,e)pyrene	<1	µg/kg	1	
	Dibenzo(a,h)pyrene	<1	µg/kg	1	
	Dibenzo(a,i)pyrene	<1	µg/kg	1	
	Dibenzo(a,l)pyrene	<1	µg/kg	1	
	Indeno(1,2,3-cd)pyrene	<0.5	µg/kg	0.5	
	Sum of all positive identified PAH	0.6	µg/kg		
	Sum PAH 4	Inapplicable	µg/kg		
☆ JC0A9	Patulin (oil) Method: Internal, LC-MS/MS				
	Patulin	<5	µg/kg	5	
☆ JCAF2	Aflatoxins B1, B2, G1, G2 (fats, oils, lecithin, egg powder) Method: internal method based on EN 14123				
	Aflatoxin B1	<0.1	µg/kg	0.1	
	Aflatoxin B2	<0.1	µg/kg	0.1	
	Aflatoxin G1	<0.1	µg/kg	0.1	
	Aflatoxin G2	<0.1	µg/kg	0.1	

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 216000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

	Results	Unit	LOQ	LOD
Sum of all positive Aflatoxins	<0.4	µg/kg		
☆ JJW2Z Sterigmatocystin Method: Internal, LC-MS/MS				
Sterigmatocystin	<10	µg/kg	10	
☆ LW0XD Domoic acid, DA Method: In house method (210), LC-MS				
Amnesic Shellfish Poison, Domoic Acid	Not Detected			
Amnesic Shellfish Poison, Domoic acid	<3.0	µg/g	3	
☆ QA00F Peroxide Value Method: AOCS Cd 8-53				
Peroxide value	1.1	meq/kg	0.1	
☆ QA00I Acid Value Method: AOCS Cd 3d-63				
Acid value (mg KOH/g)	0.38	mg KOH/g	0.05	
Free fatty acids (as oleic acid)	0.19	%	0.01	
☆ QA01L p-Anisidine Value Method: AOCS Cd 18-90				
p-Anisidine Value	2.8		1	
☆ QA02L Color (Lovibond Scale) Method: AOCS Cc 13e-92; ISO 15305				
Color, red scale, 1 inch cell path	0.9			
Color, yellow scale, 1 inch cell path	9			
☆ QA034 Fumonisins (IAC-LC-MSMS) Method: JAOAC, 92 (2), 496.				
Fumonisin (B1+B2+B3)	<30	µg/kg	30	
Fumonisin B1	<10	µg/kg	10	
Fumonisin B2	<10	µg/kg	10	
Fumonisin B3	<10	µg/kg	10	
☆ QA04E Residual Solvents (GC-MS) Method: AOCS Cg 4-94				
1,1,1-Trichloroethane	<0.2	mg/kg	0.2	
1,1,2-Trichloroethane	<0.2	mg/kg	0.2	
1,2-Dichloroethane	<0.5	mg/kg	0.5	
1,2-Dimethoxyethane	<1	mg/kg	1	
1-Butanol	<1	mg/kg	1	
2-Hexanone	<1	mg/kg	1	
Acetone	<1	mg/kg	1	
Benzene	<0.1	mg/kg	0.1	
Butyl acetate	<0.5	mg/kg	0.5	
Carbon tetrachloride	<0.5	mg/kg	0.5	
Chlorobenzene	<0.5	mg/kg	0.5	
Chloroform	<0.1	mg/kg	0.1	
Cyclohexane	<0.2	mg/kg	0.2	
Dichloromethane	<0.1	mg/kg	0.1	
Ethanol	<1	mg/kg	1	
Ethyl acetate	<1	mg/kg	1	
Heptane	<0.2	mg/kg	0.2	
Hexane (sum of n-hexane, iso and 3-methyl pentane)	<0.5	mg/kg	0.5	
Isopropanol	<1	mg/kg	1	
Methanol	<1	mg/kg	1	
Methyl Ethyl Ketone (MEK)	<0.2	mg/kg	0.2	
Methyl-tert-butylether (MTBE)	<0.2	mg/kg	0.2	
Tetralin	<5	mg/kg	5	
Toluene	<0.2	mg/kg	0.2	
Trichloroethylene	<0.1	mg/kg	0.1	
Xylenes (sum)	<0.2	mg/kg	0.2	
☆ QA062 Polychlorinated Biphenyls (Oils & Fats) Method: ASU L00.00-34				
PCB 1	<0.01	mg/kg	0.01	
PCB 101	<0.01	mg/kg	0.01	
PCB 104	<0.01	mg/kg	0.01	
PCB 105	<0.01	mg/kg	0.01	

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 216000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

		Results	Unit	LOQ	LOD
	PCB 118	<0.01	mg/kg	0.01	
	PCB 126	<0.01	mg/kg	0.01	
	PCB 128	<0.01	mg/kg	0.01	
	PCB 138	<0.01	mg/kg	0.01	
	PCB 153	<0.01	mg/kg	0.01	
	PCB 170	<0.01	mg/kg	0.01	
	PCB 18	<0.01	mg/kg	0.01	
	PCB 180	<0.01	mg/kg	0.01	
	PCB 187	<0.01	mg/kg	0.01	
	PCB 188	<0.01	mg/kg	0.01	
	PCB 195	<0.01	mg/kg	0.01	
	PCB 201	<0.01	mg/kg	0.01	
	PCB 206	<0.01	mg/kg	0.01	
	PCB 209	<0.01	mg/kg	0.01	
	PCB 28	<0.01	mg/kg	0.01	
	PCB 29	<0.01	mg/kg	0.01	
	PCB 44	<0.01	mg/kg	0.01	
	PCB 50	<0.01	mg/kg	0.01	
	PCB 52	<0.01	mg/kg	0.01	
	PCB 66	<0.01	mg/kg	0.01	
	PCB 77	<0.01	mg/kg	0.01	
	PCB 8	<0.01	mg/kg	0.01	
	PCB 87	<0.01	mg/kg	0.01	
	Sum Non-Dioxin-Like PCBs (28+52+101+138+153+180)	<0.01	mg/kg	0.01	
	Total PCB	<0.1	mg/kg	0.1	
☆ QA0MT	Ochratoxin A (HPLC-FLD) Method: AOAC 2000.16				
	Ochratoxin A	<1	µg/kg	1	
☆ QA23L	Trans Fatty Acids, relative area % (GC-FID) Method: AOCS Ce 1f-96				
	Total Trans Fatty Acids	<0.01	% of fatty acids	0.01	
	total trans fatty acids C18:1	<0.01	% of fatty acids	0.01	
	total trans fatty acids C18:2 (without CLA)	<0.01	% of fatty acids	0.01	
	total trans fatty acids C18:2 + C18:3	<0.01	% of fatty acids	0.01	
	total trans fatty acids C18:3	<0.01	% of fatty acids	0.01	
☆ QA282	Free Fatty Acid, as Oleic Method: AOCS Ca 5a-40				
	Free fatty acids as oleic acid	0.14	%	0.01	
☆ QA328	Insoluble Impurities Method: AOCS Ca 3a-46				
	Insoluble impurities	<0.01	%	0.01	
☆ QA513	Toxaphene (GC-MSMS)				
	Toxaphene Parlar 26	<LOQ	mg/kg	0.01	
	Toxaphene Parlar 50	<LOQ	mg/kg	0.01	
	Toxaphene Parlar 62	Not Analyzable	mg/kg	0.01	
☆ QA560	Sulfallate (Vegedex)				
	Sulfallate (Vegedex)	<0.02	mg/kg	0.02	
☆ QA867	Silicon (ICP-AES) Method: AOCS Ca 17-01				
	Silicon (Si)	<1	mg/kg	1	
☆ QA967	Unsaponifiable Matter (Ethyl ether ext) Method: AOCS Ca 6b-53				
	Unsaponifiable matter	1.03	%	0.05	
☆ QAA07	Vomitoxin (Deoxynivalenol, DON) LC-MSMS Method: Food Addit Contam Part A, 2013:30(3),541-9.				

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

	Results	Unit	LOQ	LOD
Vomitoxin (Deoxynivalenol)	<50	µg/kg	50	
☆ QAA19 Zearalenone (LC-MS/MS) Method: Food Addit Contam Part A, 2013:30(3),641-9.				
Zearalenone	<25	µg/kg	25	
☆ QD089 Fatty Acids-Omega 6 & 3 %W/W Method: AOCS Ce 2-66 AOCS Ce 1-62				
C08:0 Octanoic (Caprylic)	<0.02	%	0.02	
C10:0 Decanoic (Capric)	<0.02	%	0.02	
C11:0 Undecanoic (Hendecanoic)	<0.02	%	0.02	
C12:0 Dodecanoic (Lauric)	0.13	%	0.02	
C14:0 Tetradecanoic (Myristic)	2.59	%	0.02	
C14:1 Tetradecenoic (Myristoleic)	<0.02	%	0.02	
C15:0 Pentadecanoic	1.32	%	0.02	
C15:1 Pentadecenoic	0.02	%	0.02	
C16:0 Hexadecanoic (Palmitic)	34.82	%	0.02	
C16:1 Hexadecenoic (Palmitoleic)	0.28	%	0.02	
C16:2 Hexadecadienoic	<0.02	%	0.02	
C16:3 Hexadecatrienoic	<0.02	%	0.02	
C16:4 Hexadecatetraenoic	<0.02	%	0.02	
C17:0 Heptadecanoic (Margaric)	0.44	%	0.02	
C17:1 Heptadecenoic (Margaroleic)	<0.02	%	0.02	
C18:0 Octadecanoic (Stearic)	1.02	%	0.02	
C18:1 Octadecenoic (Oleic + isomers)	0.44	%	0.02	
C18:2 Octadecadienoic (Linoleic + isomers)	0.84	%	0.02	
C18:2 Octadecadienoic Omega 6 (Linoleic)	0.78	%	0.02	
C18:3 Octadecatrienoic (Linolenic + isomers)	0.19	%	0.02	
C18:3 Octadecatrienoic Omega 3 (Alpha Linolenic)	0.13	%	0.02	
C18:3 Octadecatrienoic Omega 6 (Gamma Linolenic)	0.06	%	0.02	
C18:4 Octadecatetraenoic Omega 3 (Stearidonic)	0.16	%	0.02	
C20:0 Eicosanoic (Arachidic)	0.13	%	0.02	
C20:1 Eicosenoic (Gondoic + isomers)	<0.02	%	0.02	
C20:2 Eicosadienoic Omega 6	<0.02	%	0.02	
C20:3 Eicosatrienoic	0.11	%	0.02	
C20:3 Eicosatrienoic Omega 3	<0.02	%	0.02	
C20:3 Eicosatrienoic Omega 6	0.10	%	0.02	
C20:4 Eicosatetraenoic (Arachidonic + isomers)	2.24	%	0.02	
C20:4 Eicosatetraenoic Omega 3	0.50	%	0.02	
C20:4 Eicosatetraenoic Omega 6 (Arachidonic)	1.74	%	0.02	
C20:5 Eicosapentaenoic Omega 3	0.46	%	0.02	
C21:5 Heneicosapentaenoic Omega 3	<0.02	%	0.02	
C22:0 Docosanoic (Behenic)	0.08	%	0.02	
C22:1 Docosenoic (Erucic + isomers)	0.04	%	0.02	
C22:2 Docosadienoic Omega 6	<0.02	%	0.02	
C22:3 Docosatrienoic, Omega 3	<0.02	%	0.02	
C22:4 Docosatetraenoic Omega 6	0.03	%	0.02	
C22:5 Docosapentaenoic	5.10	%	0.02	
C22:5 Docosapentaenoic Omega 3	0.11	%	0.02	
C22:5 Docosapentaenoic Omega 6	4.99	%	0.02	

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 216000
Jiangsu Province, P.R.China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

Page 6/7
PR-19-SU-000048-01

	Results	Unit	LOQ	LOD
C22:6 Docosahexaenoic Omega 3	38.30	%	0.02	
C24:0 Tetracosanoic (Lignoceric)	0.06	%	0.02	
C24:1 Tetracosenoic (Nervonic)	<0.02	%	0.02	
Sum of Omega 3 Isomers	39.67	%	0.05	
Sum of Omega 6 Isomers	7.71	%	0.05	
Total Fat as Triglycerides	92.76	%	0.1	
Total Fatty Acids Calc.	88.85	%	0.1	
Total Monounsaturated Fatty Acids	0.80	%	0.05	
Total Polyunsaturated Fatty Acids	47.44	%	0.05	
Total Saturated Fatty Acids	40.61	%	0.05	
☆ QD153 Moisture by Karl Fischer Method: AOCS Ca 2e-84				
Moisture, Karl Fischer	0.01	%	0.01	
☆ SFFED Pesticide screening using LC/MS/MS in fatty food Selected Parameter(s) Method: § 64 LFGB L 13.04-5 : 2013-08, mod.				
Linuron	<0.01	mg/kg	0.01	
Bromacil	<0.01	mg/kg	0.01	
Pyrethrins	<0.1	mg/kg	0.1	
☆ UMBYM Yeast-Mould E <10 >1500 /g (1) PCCG-P AOAC 997.02 Method: AOAC 997.02				
Moulds	<10	cfu/g		
Yeast	<10	cfu/g		
☆ UMCP8 Salmonella D Abs Pres /25 ml AOAC-RI 121601 Method: AOAC-RI 121601				
Salmonella	Not Detected	/25 ml		
☆ UMM1D Coliforms /ml AOAC 991.14 Method: AOAC 991.14				
Coliforms	<10	cfu/ml		

COMMENT

The content of total plant sterols and plant stanols does not contain cholesterol and non-4-desmethyl sterols (i.e. cycloartenol, 24-methylenecycloartanol, and citrostadienol).

Amount of total GC-eutables is 0,491 mg/100 g.

List of screened molecules (* = limit of quantification)

SUS1A Pesticide Screening(GC) (LOQ* mg/kg)

(a) 3-Phenylphenol (0.01)	(a) Acetochlor (0.05)	(a) Aclonifen (0.05)	(a) Aldrin (0.01)	(a) Ametryne (0.02)	(a) Amidite (0.04)
(a) Atrazine (0.02)	(a) Benfluralin (0.01)	(a) Bifenox (0.05)	(a) Bifenthrin (0.01)	(a) Biphenyl (0.01)	(a) Bromfenvinfos (0.02)
(a) Bromophos (0.01)	(a) Bromophos-ethyl (0.01)	(a) Bromopropylate (0.01)	(a) Butachlor (0.01)	(a) Butafenacil (0.01)	(a) Cadusafos (0.02)
(a) Captafol (0.05)	(a) Captan (0.04)	(a) Captan/ThiPh (Sum calculated as Captan) ()	(a) Carbophenothion (0.05)	(a) Carbophenothion-methyl (0.05)	(a) Carbofuran (0.05)
(a) Chlorbenside (0.05)	(a) Chlordane (Sum) ()	(a) Chlordane, alpha (0.01)	(a) Chlordane, gamma (0.01)	(a) Chlorfenapyr (0.05)	(a) Chlorfenson (0.05)
(a) Chlorfenvinphos (0.01)	(a) Chlormephos (0.05)	(a) Chlorobenzilate (0.01)	(a) Chloroneb (0.01)	(a) Chloropropylate (0.01)	(a) Chlorothalonil (0.01)
(a) Chlorpyrifos (-ethyl) (0.01)	(a) Chlorpyrifos-methyl (0.01)	(a) Chlorthal-dimethyl (0.01)	(a) Chlorthion (0.05)	(a) Chlozolinate (0.02)	(a) Cruformate (0.05)
(a) Cyanazine (0.02)	(a) Cyanofenphos (0.05)	(a) Cyanophos (0.02)	(a) Cyfluthrin (0.05)	(a) Cyhalothrin, lambda-(incl. Cyhalothrin, gamma-) (0.01)	(a) Cypermethrin (0.05)
(a) Cyphenothrin (0.05)	(a) DDD, o,p'- (0.01)	(a) DDD, p,p'- (0.01)	(a) DDE, o,p'- (0.01)	(a) DDE, p,p'- (0.01)	(a) DDT (Sum) ()
(a) DDT, o,p'- (0.01)	(a) DDT, p,p'- (0.01)	(a) Deltamethrin (0.05)	(a) Dichlobenil (0.05)	(a) Dichlofenthion (0.02)	(a) Dichlofluanid (0.02)
(a) Dichlorobenzophenone o,p' (0.02)	(a) Dichlorobenzophenone p,p' (0.02)	(a) Dichlorvos (0.05)	(a) Diclofen (0.05)	(a) Diclofol (Sum) ()	(a) Diclofol, o,p'- (0.02)
(a) Diclofol, p,p'- (0.02)	(a) Dieldrin (0.02)	(a) Dieldrin (Sum) ()	(a) Dienochlor (0.05)	(a) Dinobuton (0.05)	(a) Dioxabenzofos (0.02)
(a) Dioxathion (0.05)	(a) Diphenylamine (0.01)	(a) Edifenphos (0.02)	(a) Endosulfan (Sum) ()	(a) Endosulfan, alpha- (0.05)	(a) Endosulfan, beta- (0.05)
(a) Endosulfan, sulfat- (0.02)	(a) Endrin (0.05)	(a) EPN (0.05)	(a) Ethalfluralin (0.01)	(a) Ethion (0.02)	(a) Etridiazole (0.02)
(a) Etrimfos (0.02)	(a) Fenarsiphos (0.05)	(a) Fenchlorphos (0.02)	(a) Fenchlorphos (sum) ()	(a) Fenchlorphos oxon (0.01)	(a) Fenfluthrin (0.01)
(a) Fenitrothion (0.02)	(a) Fenpropathrin (0.02)	(a) Fenson (0.02)	(a) Fenthion (0.02)	(a) Fenvalerate & Esfenvalerate (Sum of RSASR isomers) (0.02)	(a) Fenvalerate & Esfenvalerate(sum of RR,SS,RS,SR) ()
(a) Fenvalerate & Esfenvalerate(Sum of RSASR isomers) (0.02)	(a) Fluchloralin (0.05)	(a) Flucythrinate (0.05)	(a) Flumetralin (0.05)	(a) Fluotrimazole (0.01)	(a) Fluquinconazole (0.02)
(a) Flusilazole-tau (0.02)	(a) Fonofos (0.02)	(a) Formothion (0.05)	(a) HCB (0.01)	(a) HCH gamma(Lindan) (0.01)	(a) HCH, alpha- (0.01)
(a) HCH, beta- (0.01)	(a) HCH, delta- (0.01)	(a) HCH, epsilon- (0.01)	(a) Heptachlor (0.01)	(a) Heptachlor (Sum) ()	(a) Heptachlor epoxide cis (0.01)
(a) Heptachlor epoxide trans (0.01)	(a) Heptenophos (0.02)	(a) Iprobenfos (0.02)	(a) Isazofos (0.01)	(a) Isocarbophos (0.02)	(a) Isodrin (0.02)
(a) Isofenphos (0.02)	(a) Isofenphos-methyl (0.01)	(a) Isoprothiolane (0.02)	(a) Jodfenphos (0.02)	(a) Kresoxim-methyl (0.01)	(a) Lindrin (0.02)
(a) Malaoxon (0.05)	(a) Malathion (0.02)	(a) Malathion (Sum) ()	(a) Mecarbam (0.04)	(a) Mepronil (0.01)	(a) Methacrifos (0.02)
(a) Methamidophos (0.1)	(a) Methidathion (0.02)	(a) Methoxychlor (0.02)	(a) Methyl-Parazhlorophenylsulfide (0.05)	(a) Metribuzin (0.04)	(a) Mevinphos (0.02)
(a) Mirex (0.01)	(a) N-Desethyl-pirimiphos-methyl (0.01)	(a) Nitrapyrin (0.01)	(a) Nitrofen (0.02)	(a) Nitrothal-isopropyl (0.01)	(a) Octachlorodipropyl ether (S-421) (0.05)
(a) Ofurace (0.01)	(a) Oxadixyon (0.02)	(a) Oxychlordane (0.02)	(a) Oxyfluorfen (0.02)	(a) Paclobutrazol (0.01)	(a) Parathion (0.01)
(a) Parathion-methyl (0.04)	(a) PCB 101 (0.01)	(a) PCB 118 (0.01)	(a) PCB 138 (0.01)	(a) PCB 153 (0.01)	(a) PCB 180 (0.01)
(a) PCB 28 (0.01)	(a) PCB 52 (0.01)	(a) Pentachloroaniline (0.01)	(a) Pentachloronitrobenzene (0.01)	(a) Pentachlorobenzene (0.01)	(a) Permethrin (0.02)
(a) Phenkapton (0.05)	(a) Phenothrin (0.01)	(a) Phenthoate (0.02)	(a) Phorate (0.04)	(a) Phosphamidon (0.04)	(a) Picoxystrobin (0.01)
(a) Piperophos (0.01)	(a) Pirimiphos-ethyl (0.01)	(a) Procymidone (0.01)	(a) Profenofos (0.01)	(a) Profluralin (0.02)	(a) Prometryn (0.02)
(a) Propanil (0.01)	(a) Propazine (0.01)	(a) Prothiofos (0.02)	(a) Pyrazophos (0.01)	(a) Pyridalyl (0.05)	(a) Pyridaphenthion (0.02)
(a) Pyrifenox (0.04)	(a) Pyrimethanil (0.01)	(a) Quinalphos (0.01)	(a) Quinoxyfene (0.01)	(a) Quizalofop-P-ethyl (0.01)	(a) Silafluofen (0.05)

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 216000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

Preliminary report

(a) Silthiofam (0.01)	(a) Tebufenpyrad (0.01)	(a) Tecnazene (0.02)	(a) Teflubenzuron (0.02)	(a) Terbufos (0.02)	(a) Tetrachlorvinphos (0.02)
(a) Tetradifon (0.02)	(a) Tetrahydrophthalimide (THPI) (0.05)	(a) Tetramethrin (0.02)	(a) Tetrasul (0.01)	(a) Tolylfluanid (0.02)	(a) Triadimefon (0.02)
(a) Triazophos (0.01)	(a) Triazophos (0.02)	(a) Trichloronat (0.01)	(a) Trifluralin (0.02)	(a) Triticonazole (0.01)	(a) Uniconazole (0.02)
(a) Vinclozolin (0.02)					

SIGNATURE

Claire Wang
Authorized Signatory

Shine Xie
Authorized Signatory

EXPLANATORY NOTE

LOQ: Limit of Quantification
< LOQ: Below Limit of Quantification
N/A means Not applicable
^ CNAS # DAKKS =CMA
☆ means the test is subcontracted within Eurofins group
° means the test is subcontracted outside Eurofins group
Sum compounds results are calculated from the results of each quantified compound as set by regulation
The result(s) relate(s) only to the item(s) tested and is(are) only for internal use by the client and not for publicly available as evidence.
This analytical report shall not be reproduced except in full, without written approval of the laboratory.
Eurofins General Terms and Conditions apply.
For and on behalf of Eurofins Technology Service (Suzhou) Co., Ltd

END OF REPORT

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 216000
Jiangsu Province, P.R. China

Phone +86 400 826 5088
Fax
www.eurofins.cn

eurofins

Certificate No.: PR-19-SU-000048-01

Physical inspection

Sample code	502-2019-00010194
Sample name	DHA oil
Color	Light yellow
Odor	Have the special odor of this product
Texture	Oily liquid

Eurofins Tech. Service (Suzhou) Co., Ltd.
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax +86 512 6878 5966
www.eurofins.cn

eurofins

CNAS 中国认可 检测 TESTING CNAS L3788

Analytical Report

Sample Code	502-2020-00006653	Report date	25-Feb-2020
Certificate No.	AR-20-SU-008353-01-EN		

HuBei Fuxing Biotechnology CO,.LTD
NO.18 Fuxing Street, Chenhu Town,
Hanchuan, Hubei Province, P.R. China
Fax 0086 712 8741718

Our reference:	502-2020-00006653/ AR-20-SU-008353-01-EN
Client Sample Code:	D19122101D
Sample described as:	二十二碳六烯酸油脂
Sample Packaging:	Sealed metal bottle
Sample reception date:	20-Jan-2020
Analysis Starting Date:	20-Jan-2020
Analysis Ending Date:	26-Feb-2020
Arrival Temperature (°C)	17.8
Sample Weight	1kg*2

		Results	Unit	LOQ	LOD
+# SU007	Mercury (AAS) Method: BS EN 13806:2002				
Mercury (Hg)		<0.005	mg/kg	0.005	
+# SU04X	Potassium (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
Potassium (K)		<3	mg/kg	3	
+# SU051	Manganese (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
Manganese (Mn)		<0.1	mg/kg	0.1	
+# SU066	Molybdenum (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
Molybdenum (Mo)		<0.03	mg/kg	0.03	
+# SU066	Nickel (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
Nickel (Ni)		<0.1	mg/kg	0.1	
+# SU06D	Lead (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
Lead (Pb)		<0.05	mg/kg	0.05	
+# SU06E	Arsenic (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
Arsenic (As)		<0.005	mg/kg	0.005	
+# SU06F	Chromium (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
Chromium (Cr)		<0.1	mg/kg	0.1	
+# SU06G	Cadmium (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
Cadmium (Cd)		<0.005	mg/kg	0.005	
+# SU06H	Iron (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
Iron (Fe)		<3	mg/kg	3	
+# SU06J	Copper (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
Copper (Cu)		<0.1	mg/kg	0.1	
+# SU06K	Phosphorus (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
Phosphorus (P)		<5	mg/kg	5	

		Results	Unit	LOQ	LOD
+# SUS1A	Pesticide Screening(GC) Method: BS EN 12393:2013				
Screened pesticides		<LOQ	mg/kg		

		Results	Unit	LOQ	LOD
+# SU10Z	Cronobacter spp. in 10g Method: ISO 22964:2017				

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China
Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins TESTING SERVICE SUZHOU CO LTD

DAkkS Deutsche Akkreditierungsstelle D-PL-14292-01-00

eurofins

	Results	Unit	LOQ	LOD
Cronobacter spp	Not Detected	/10 ml		

	Results	Unit	LOQ	LOD
+# SU20L Protein Method: AOAC 984.13				
Protein	<0.1	g/100 g	0.1	
Protein Factor	6.25			
SU217 Physical inspection Method: Internal Method, Organoleptic evaluation				
Physical inspection	see attached document			
+# SU227 Ash Method: AOAC 941.12; AOAC 923.03				
Ash	0.020	g/100 g	0.01	
+# SU372 Cholesterol Method: AOAC 994.10 mod.				
Cholesterol	2928	mg/kg	10	

	Results	Unit	LOQ	LOD
☆ SF0XA add 1 on to the GC/MS-pesticide screening Selected Parameter(s) Method: § 64 LFGB L 00.00-34 : 2010-09, mod.				
Tralomethrin	<LOQ	mg/kg	0.05	
☆ FL023 Plant sterols and plant stanols (not enriched) Method: NMKL 198:2014				
Brassicasterol	15	mg/100 g	1	
Cholesterol	279	mg/100 g	1	
Campesterol	8	mg/100 g	1	
Campestanol	7	mg/100 g	1	
Stigmasterol	38	mg/100 g	1	
Unidentified sterols	237	mg/100 g	1	
Sitosterol	79	mg/100 g	1	
Sitostanol+ delta-5-avenasterol	10	mg/100 g	1	
Delta-5,24-stigmastadienol	11	mg/100 g	1	
Delta-7-stigmastenol	24	mg/100 g	1	
delta-7-Avenasterol	12	mg/100 g	1	
Cycloartenol	Not Detected	mg/100 g	1	
24-Methylenecycloartanol	3	mg/100 g	1	
Citrostadienol	Not Detected	mg/100 g	1	
Total plant sterols + plant stanols	440	mg/100 g	1	
☆ DJ454 Sulphur (S) Method: EN 13805:2014, EN ISO 11885m:2009				
Sulphur (S)	< 20	mg/kg	20	
☆ JJ006 Aflatoxins B1, B2, G1, G2 (food) Method: DIN EN 14123 (2008-03), mod.				
Aflatoxin B1	<0.1	µg/kg	0.1	
Aflatoxin B2	<0.1	µg/kg	0.1	
Aflatoxin G1	<0.1	µg/kg	0.1	
Aflatoxin G2	<0.1	µg/kg	0.1	
Sum of all positive Aflatoxins	<0.4	µg/kg		
☆ JJW2Z Sterigmatocystin Method: Internal, LC-MS/MS				
Sterigmatocystin	<10	µg/kg	10	
☆ LW0XD Domoic acid, DA Method: In house method (210), LC-MS				
Amnesic Shellfish Poison, Domoic acid	<3.0	µg/g	3	
Amnesic Shellfish Poison, Domoic Acid	Not Detected			
☆ QA00F Peroxide Value Method: AOCS Cd 8-53				
Peroxide value	1.9	meq/kg	0.1	
☆ QA00I Acid Value Method: AOCS Cd 3d-63				
Acid value (mg KOH/g)	0.14	mg KOH/g	0.05	
Free fatty acids (as oleic acid)	0.07	%	0.01	
☆ QA01L p-Anisidine Value Method: AOCS Cd 18-90				
p-Anisidine Value	8.2		1	
☆ QA02L Color (Lovibond Scale) Method: AOCS Cc 13e-92; ISO 15305				
Color, red scale, 5.25 inch cell path	1.7			
Color, yellow scale, 5.25 inch cell path	17			
☆ QA034 Fumonisins (IAC-LC-MSMS) Method: JAOAC, 92 (2), 496.				

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 628 5088
Fax
www.eurofins.cn

eurofins

		Results	Unit	LOQ	LOD
	Fumonisin (B1+B2+B3)	<30	µg/kg	30	
	Fumonisin B1	<10	µg/kg	10	
	Fumonisin B2	<10	µg/kg	10	
	Fumonisin B3	<10	µg/kg	10	
☆ QA04E	Residual Solvents (GC-MS) Method: AOCS Cg 4-94				
	1,1,1-Trichloroethane	<0.2	mg/kg	0.2	
	1,1,2-Trichloroethane	<0.2	mg/kg	0.2	
	1,2-Dichloroethane	<0.5	mg/kg	0.5	
	1,2-Dimethoxyethane	<1.0	mg/kg	1	
	1-Butanol	<1.0	mg/kg	1	
	2-Hexanone	<1.0	mg/kg	1	
	Acetone	<1.0	mg/kg	1	
	Benzene	<0.10	mg/kg	0.1	
	Butyl acetate	<0.50	mg/kg	0.5	
	Carbon tetrachloride	<0.50	mg/kg	0.5	
	Chlorobenzene	<0.50	mg/kg	0.5	
	Chloroform	<0.10	mg/kg	0.1	
	Cyclohexane	<0.20	mg/kg	0.2	
	Dichloromethane	<0.10	mg/kg	0.1	
	Ethanol	10.3	mg/kg	1	
	Ethyl acetate	<1.0	mg/kg	1	
	Heptane	<0.20	mg/kg	0.2	
	Hexane (sum of n-hexane, iso and 3-methyl pentane)	<0.50	mg/kg	0.5	
	Isopropanol	<1.0	mg/kg	1	
	Methanol	<1.0	mg/kg	1	
	Methyl Ethyl Ketone (MEK)	<0.20	mg/kg	0.2	
	Methyl-tert-butylether (MTBE)	<0.20	mg/kg	0.2	
	Tetralin	<5.0	mg/kg	5	
	Toluene	<0.20	mg/kg	0.2	
	Trichloroethylene	<0.10	mg/kg	0.1	
	Xylenes (sum)	<0.20	mg/kg	0.2	
☆ QA06Z	Polychlorinated Biphenyls (Oils & Fats) Method: ASU L00.00-34				
	PCB 1	<0.01	mg/kg	0.01	
	PCB 101	<0.01	mg/kg	0.01	
	PCB 104	<0.01	mg/kg	0.01	
	PCB 105	<0.01	mg/kg	0.01	
	PCB 118	<0.01	mg/kg	0.01	
	PCB 126	<0.01	mg/kg	0.01	
	PCB 128	<0.01	mg/kg	0.01	
	PCB 138	<0.01	mg/kg	0.01	
	PCB 153	<0.01	mg/kg	0.01	
	PCB 170	<0.01	mg/kg	0.01	
	PCB 18	<0.01	mg/kg	0.01	
	PCB 180	<0.01	mg/kg	0.01	
	PCB 187	<0.01	mg/kg	0.01	
	PCB 188	<0.01	mg/kg	0.01	
	PCB 195	<0.01	mg/kg	0.01	
	PCB 201	<0.01	mg/kg	0.01	
	PCB 206	<0.01	mg/kg	0.01	
	PCB 209	<0.01	mg/kg	0.01	
	PCB 28	<0.01	mg/kg	0.01	
	PCB 29	<0.01	mg/kg	0.01	

Eurofins Tech. Service (Suzhou) Co. Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

		Results	Unit	LOQ	LOD
	PCB 44	<0.01	mg/kg	0.01	
	PCB 50	<0.01	mg/kg	0.01	
	PCB 52	<0.01	mg/kg	0.01	
	PCB 66	<0.01	mg/kg	0.01	
	PCB 77	<0.01	mg/kg	0.01	
	PCB 8	<0.01	mg/kg	0.01	
	PCB 87	<0.01	mg/kg	0.01	
	Sum Non-Dioxin-Like PCBs (28+52+101+138+153+180)	<0.01	mg/kg	0.01	
	Total PCB	<0.10	mg/kg	0.1	
☆ QA0MT	Ochratoxin A (HPLC-FLD) Method: AOAC 2000.16				
	Ochratoxin A	<5.0	µg/kg	1	
☆ QA23L	Trans Fatty Acids, relative area % (GC-FID) Method: AOCS Ce 1f-96				
	Total Trans Fatty Acids	0.07	% of fatty acids	0.01	
	total trans fatty acids C18:1	<0.01	% of fatty acids	0.01	
	total trans fatty acids C18:2 (without CLA)	0.07	% of fatty acids	0.01	
	total trans fatty acids C18:2 + C18:3	0.07	% of fatty acids	0.01	
	total trans fatty acids C18:3	<0.01	% of fatty acids	0.01	
☆ QA282	Free Fatty Acid, as Oleic Method: AOCS Ca 5a-40				
	Free fatty acids as oleic acid	0.07	%	0.01	
☆ QA328	Insoluble Impurities Method: AOCS Ca 3a-46				
	Insoluble impurities	0.02	%	0.01	
☆ QA513	Toxaphene (GC-MSMS)				
	Toxaphene Parlar 26	<LOQ	mg/kg	0.01	
	Toxaphene Parlar 50	<LOQ	mg/kg	0.01	
	Toxaphene Parlar 62	<LOQ	mg/kg	0.01	
☆ QA550	Sulfallate (Vegedex)				
	Sulfallate (Vegedex)	<LOQ	mg/kg	0.02	
☆ QA867	Silicon (ICP-AES) Method: AOCS Ca 17-01				
	Silicon (Si)	<1.0	mg/kg	1	
☆ QA967	Unsaponifiable Matter (Ethyl ether ext) Method: AOCS Ca 6b-53				
	Unsaponifiable matter	1.87	%	0.05	
☆ QAA07	Vomitoxin (Deoxynivalenol, DON) LC-MSMS Method: Food Addit Contam Part A, 2013;30(3),641-9.				
	Vomitoxin (Deoxynivalenol)	<10	µg/kg	10	
☆ QAA19	Zearalenone (LC-MSMS) Method: Food Addit Contam Part A, 2013;30(3),641-9.				
	Zearalenone	<5.0	µg/kg	5	
☆ QD089	Fatty Acids-Omega 6 & 3 %W/W Method: AOCS Ce 2-66 mod., AOCS Ce 1b-89 mod.				
	C08:0 Octanoic (Caprylic)	<0.02	%	0.02	
	C10:0 Decanoic (Capric)	<0.02	%	0.02	
	C11:0 Undecanoic (Hendecanoic)	<0.02	%	0.02	
	C12:0 Dodecanoic (Lauric)	0.04	%	0.02	
	C14:0 Tetradecanoic (Myristic)	0.35	%	0.02	
	C14:1 Tetradecenoic (Myristoleic)	<0.02	%	0.02	
	C15:0 Pentadecanoic	1.04	%	0.02	
	C15:1 Pentadecenoic	<0.02	%	0.02	
	C16:0 Hexadecanoic (Palmitic)	17.10	%	0.02	
	C16:1 Hexadecenoic (Palmitoleic)	0.12	%	0.02	
	C16:2 Hexadecadienoic	<0.02	%	0.02	
	C16:3 Hexadecatrienoic	<0.02	%	0.02	
	C16:4 Hexadecatetraenoic	<0.02	%	0.02	

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China
Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

	Results	Unit	LOQ	LOD
C17:0 Heptadecanoic (Margaric)	1.36	%	0.02	
C17:1 Heptadecenoic (Margaroleic)	<0.02	%	0.02	
C18:0 Octadecanoic (Stearic)	1.09	%	0.02	
C18:1 Octadecenoic (Oleic + isomers)	1.71	%	0.02	
C18:2 Octadecadienoic (Linoleic + isomers)	4.09	%	0.02	
C18:2 Octadecadienoic Omega 6 (Linoleic)	4.01	%	0.02	
C18:3 Octadecatrienoic (Linolenic + isomers)	0.83	%	0.02	
C18:3 Octadecatrienoic Omega 3 (Alpha Linolenic)	0.62	%	0.02	
C18:3 Octadecatrienoic Omega 6 (Gamma Linolenic)	0.21	%	0.02	
C18:4 Octadecatetraenoic Omega 3 (Stearidonic)	0.13	%	0.02	
C20:0 Eicosanoic (Arachidic)	0.22	%	0.02	
C20:1 Eicosenoic (Gondoic + isomers)	0.04	%	0.02	
C20:2 Eicosadienoic Omega 6	0.03	%	0.02	
C20:3 Eicosatrienoic	0.30	%	0.02	
C20:3 Eicosatrienoic Omega 3	<0.02	%	0.02	
C20:3 Eicosatrienoic Omega 6	0.29	%	0.02	
C20:4 Eicosatetraenoic (Arachidonic + isomers)	1.17	%	0.02	
C20:4 Eicosatetraenoic Omega 3	0.60	%	0.02	
C20:4 Eicosatetraenoic Omega 6 (Arachidonic)	0.57	%	0.02	
C20:5 Eicosapentaenoic Omega 3	0.26	%	0.02	
C21:5 Heneicosapentaenoic Omega 3	<0.02	%	0.02	
C22:0 Docosanoic (Behenic)	0.14	%	0.02	
C22:1 Docosenoic (Erucic + isomers)	<0.02	%	0.02	
C22:2 Docosadienoic Omega 6	<0.02	%	0.02	
C22:3 Docosatrienoic, Omega 3	<0.02	%	0.02	
C22:4 Docosatetraenoic Omega 6	0.07	%	0.02	
C22:5 Docosapentaenoic	12.61	%	0.02	
C22:5 Docosapentaenoic Omega 3	0.11	%	0.02	
C22:5 Docosapentaenoic Omega 6	12.50	%	0.02	
C22:6 Docosahexaenoic Omega 3	40.95	%	0.02	
C24:0 Tetracosanoic (Lignoceric)	<0.02	%	0.02	
C24:1 Tetracosenoic (Nervonic)	<0.02	%	0.02	
Sum of Omega 3 Isomers	42.69	%	0.05	
Sum of Omega 6 Isomers	17.68	%	0.05	
Total Fat as Triglycerides	87.19	%	0.1	
Total Fatty Acids Calc.	83.68	%	0.1	
Total Monounsaturated Fatty Acids	1.88	%	0.05	
Total Polyunsaturated Fatty Acids	60.45	%	0.05	
Total Saturated Fatty Acids	21.36	%	0.05	
☆ QD163 Moisture by Karl Fischer Method: AOCS Ca 2e-84				
Moisture, Karl Fischer	0.04	%	0.01	
☆ SFLKD Pesticide screening using LC/MS/MS in complex food Selected Parameter(s) Method: Internal Method, LC-MS/MS				
Linuron	<LOQ	mg/kg	0.05	
Bromacil	<LOQ	mg/kg	0.1	
Pyrethrins	<LOQ	mg/kg	5	
☆ UM6Y6 Aerobic Plate Count /ml AOAC 990.12 Method: AOAC 990.12				

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

eurofins

		Results	Unit	LOQ	LOD
	Aerobic Plate Count	10(est)	cfu/ml		
☆ UMBYM	Yeast-Mould E <10 >1500 /g (1) PCCG-P AOAC 997.02 Method: AOAC 997.02				
	Moulds	< 10	cfu/g		
	Yeast	< 10	cfu/g		
☆ UMCP8	Salmonella D Abs Pres /25 ml AOAC-RI 121601 Method: AOAC-RI 121601				
	Salmonella	Not Detected	/25 ml		
☆ UMM1D	Coliforms /ml AOAC 991.14 Method: AOAC 991.14				
	Coliforms	<10	cfu/ml		

COMMENT

Sum of total GC-elutables is 1217 mg/100 g.

The content of total plant sterols and plant stanols does not contain cholesterol and non-4-desmethyl sterols (i.e. cycloartenol, 24-methylenecycloartanol, and citrostadienol).

List of screened molecules (* = limit of quantification)

SUS1A Pesticide Screening(GC) (LOQ* mg/kg)

(a) 2-Phenylphenol (0.01)	(a) Acetochlor (0.05)	(a) Aclonifen (0.05)	(a) Aldrin (0.01)	(a) Ametryne (0.02)	(a) Aramite (0.04)
(a) Atrazine (0.02)	(a) Benfluralin (0.01)	(a) Bifenox (0.05)	(a) Bifenthrin (0.01)	(a) Biphenyl (0.01)	(a) Bromfenvinfos (0.02)
(a) Bromophos (0.01)	(a) Bromophos-ethyl (0.01)	(a) Bromopropylate (0.01)	(a) Butachlor (0.01)	(a) Butafenacil (0.01)	(a) Cadusafos (0.02)
(a) Captafol (0.05)	(a) Captan (0.05)	(a) Captan/THPI (Sum calculated as Captan) ()	(a) Carbophenothion (0.05)	(a) Carbophenothion-methyl (0.05)	(a) Carboxin (0.05)
(a) Chlorbenside (0.05)	(a) Chlordane (Sum) ()	(a) Chlordane, alpha (0.01)	(a) Chlordane, gamma (0.01)	(a) Chlorfenapyr (0.05)	(a) Chlorfenson (0.05)
(a) Chlorfenvinphos (0.01)	(a) Chlormephos (0.05)	(a) Chlorobenzilate (0.01)	(a) Chloroneb (0.01)	(a) Chloropropylate (0.01)	(a) Chlorothalonil (0.01)
(a) Chlorpyrifos (-ethyl) (0.01)	(a) Chlorpyrifos-methyl (0.01)	(a) Chlorthal-dimethyl (0.01)	(a) Chlorthion (0.05)	(a) Chlozolinate (0.02)	(a) Crufomate (0.05)
(a) Cyanazine (0.02)	(a) Cyanofenphos (0.05)	(a) Cyanophos (0.02)	(a) Cyfluthrin (0.05)	(a) Cyhalothrin, lambda- (incl. Cyhalothrin, gamma-) (0.01)	(a) Cypermethrin (0.05)
(a) Cyphenothrin (0.05)	(a) DDD, o,p'- (0.01)	(a) DDD, p,p'- (0.01)	(a) DDE, o,p'- (0.01)	(a) DDE, p,p'- (0.01)	(a) DDT (Sum) ()
(a) DDT, o,p'- (0.01)	(a) DDT, p,p'- (0.01)	(a) Deltamethrin (0.05)	(a) Dichlobenil (0.05)	(a) Dichlofenthion (0.02)	(a) Dichlofluanid (0.02)
(a) Dichlorobenzophenone o,p' (0.02)	(a) Dichlorobenzophenone p,p' (0.02)	(a) Dichlorvos (0.05)	(a) Dicloran (0.05)	(a) Dicofol (Sum) ()	(a) Dicofol, o,p'- (0.02)
(a) Dicofol, p,p'- (0.02)	(a) Dieldrin (0.02)	(a) Dieldrin (Sum) ()	(a) Dienochlor (0.05)	(a) Dinobuton (0.05)	(a) Dioxabenzofos (0.02)
(a) Dioxathion (0.05)	(a) Diphenylamine (0.01)	(a) Edifenphos (0.02)	(a) Endosulfan (Sum) ()	(a) Endosulfan, alpha- (0.05)	(a) Endosulfan, beta- (0.05)
(a) Endosulfan, sulfat- (0.02)	(a) Endrin (0.05)	(a) EPN (0.05)	(a) Ethalfluralin (0.01)	(a) Ethion (0.02)	(a) Etridiazole (0.02)
(a) Etrimfos (0.02)	(a) Fenamiphos (0.05)	(a) Fenchlorphos (0.02)	(a) Fenchlorphos (sum) ()	(a) Fenchlorphos oxon (0.01)	(a) Fenfluthrin (0.01)
(a) Fenitrothion (0.02)	(a) Fenpropathrin (0.02)	(a) Fenson (0.02)	(a) Fenthion (0.02)	(a) Fenvalerate & Esfenvalerate (Sum of RS&SR isomers) (0.02)	(a) Fenvalerate & Esfenvalerate(sum of RR,SS,RS,SR) ()
(a) Fenvalerate & Esfenvalerate(Sum of RR&SS isomers) (0.02)	(a) Fluchloralin (0.05)	(a) Flucythrinate (0.05)	(a) Flumetralin (0.05)	(a) Fluotrimazole (0.01)	(a) Fluquinconazole (0.02)
(a) Fluvalinate-tau (0.02)	(a) Fonofos (0.02)	(a) Formothion (0.05)	(a) HCB (0.01)	(a) HCH gamma(Lindan) (0.01)	(a) HCH, alpha- (0.01)
(a) HCH, beta- (0.01)	(a) HCH, delta- (0.01)	(a) HCH, epsilon- (0.01)	(a) Heptachlor (0.01)	(a) Heptachlor (Sum) ()	(a) Heptachlor epoxide cis (0.01)
(a) Heptachlor epoxide trans (0.01)	(a) Heptenophos (0.02)	(a) Iprobenfos (0.02)	(a) Isazofos (0.01)	(a) Isocarbophos (0.02)	(a) Isodrin (0.02)
(a) Isofenphos (0.02)	(a) Isofenphos-methyl (0.01)	(a) Isoprothiolane (0.02)	(a) Jodfenphos (0.02)	(a) Kresoxim-methyl (0.01)	(a) Landrin (0.02)
(a) Malaoxon (0.05)	(a) Malathion (0.02)	(a) Malathion (Sum) ()	(a) Mecarbam (0.04)	(a) Mepronil (0.01)	(a) Methacrifos (0.02)
(a) Methamidophos (0.1)	(a) Methidathion (0.02)	(a) Methoxychlor (0.02)	(a) Methyl-Pentachlorophenylsulfide (0.05)	(a) Metribuzin (0.04)	(a) Mevinphos (0.02)
(a) Mirex (0.01)	(a) N-Desethyl-pirimiphos-methyl (0.01)	(a) Nitrapyrin (0.01)	(a) Nitrofen (0.02)	(a) Nitrothal-isopropyl (0.01)	(a) Octachlorodipropyl ether (S-421) (0.05)
(a) Ofurace (0.01)	(a) Oxadiazon (0.02)	(a) Oxychlordane (0.02)	(a) Oxyfluorfen (0.02)	(a) Paclobutrazol (0.01)	(a) Parathion (0.01)
(a) Parathion-methyl (0.04)	(a) PCB 101 (0.01)	(a) PCB 118 (0.01)	(a) PCB 138 (0.01)	(a) PCB 153 (0.01)	(a) PCB 180 (0.01)
(a) PCB 28 (0.01)	(a) PCB 52 (0.01)	(a) Pentachloroaniline (0.01)	(a) Pentachloroanisole (0.01)	(a) Pentachlorobenzene (0.01)	(a) Permethrin (0.02)
(a) Phenkapton (0.05)	(a) Phenothrin (0.01)	(a) Phenthoate (0.02)	(a) Phorate (0.04)	(a) Phosphamidon (0.04)	(a) Picoxystrobin (0.01)
(a) Piperophos (0.01)	(a) Pirimiphos-ethyl (0.01)	(a) Procymidone (0.01)	(a) Profenofos (0.01)	(a) Profluralin (0.02)	(a) Prometryn (0.02)
(a) Propanil (0.01)	(a) Propazine (0.01)	(a) Prothiofos (0.02)	(a) Pyrazophos (0.01)	(a) Pyridalyl (0.05)	(a) Pyridaphenthion (0.02)
(a) Pyrifenox (0.04)	(a) Pyrimethanil (0.01)	(a) Quinalphos (0.01)	(a) Quintozene (0.01)	(a) Quizalofop-P-ethyl (0.01)	(a) Silafluofen (0.05)
(a) Silthiofam (0.01)	(a) Tebufenpyrad (0.01)	(a) Tecnazene (0.02)	(a) Tefluthrin (0.02)	(a) Terbufos (0.02)	(a) Tetrachlorvinphos (0.02)
(a) Tetradifon (0.02)	(a) Tetrahydrophthalimide (THPI) (0.05)	(a) Tetramethrin (0.02)	(a) Tetrasul (0.01)	(a) Tolylfluanid (0.02)	(a) Triallate (0.02)
(a) Triazamate (0.01)	(a) Triazophos (0.02)	(a) Trichloronat (0.01)	(a) Trifluralin (0.02)	(a) Triticonazole (0.01)	(a) Uniconazole (0.02)
(a) Vinclozolin (0.02)					

SIGNATURE

Jack He	Leo Chen	Shine Xie
Authorized Signatory	Authorized Signatory	Authorized Signatory

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

EXPLANATORY NOTE

LOQ: Limit of Quantification
< LOQ: Below Limit of Quantification
N/A means Not applicable
CNAS # DAKKS =CMA
☆ means the test is subcontracted within Eurofins group
° means the test is subcontracted outside Eurofins group
Sum compounds results are calculated from the results of each quantified compound as set by regulation
The sample description and information are provided by the Client. Eurofins is not responsible for verifying the accuracy, relevancy, adequacy and/or completeness of the information provided by the Client.
The analytical result herein is applicable for the sample(s) tested only.
This analytical report shall not be excerpted or modified without prior written approval from Eurofins. The report shall be utilized in full.
The result(s) is(are) only for internal use by the client and not for publicly available as evidence.Without the written permission of Eurofins, any party is prohibited from using the test results and the report for publicity or promotions or marketing.
The Eurofins General Terms and Conditions apply to this analytical report.
For and on behalf of Eurofins Technology Service (Suzhou) Co., Ltd

END OF REPORT

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

Phone +86 400 828 5088
Fax
www.eurofins.cn

Appendix B. Identification of Hubei Fuxing's DHF Strain.

China Center for Type Culture Collection (CCTCC) Report No. 2019027. 2019

No: 2019027

中 国 典 型 培 养 物 保 藏 中 心

China Center for Type Culture Collection (CCTCC)

Test report

April 3,2019

China Center for Type Culture Collection (CCTCC)

第 1 页 共 6 页

Test report

Sample origin: HuBei Fuxing Biotechnology CO., LTD

Sample name: Slant spawn Samples number: 1 strains

Inspection time: March, 2019 Detection typ: Consignation testing

Appraiser: Mingjin Sun Person in charge: Fang Peng

Hubei Fuxing Biotechnology Co., Ltd. commissioned a typical Chinese Culture Preservation Center to identify the isolated strains. The samples submitted for the slant are 1 strains, and the strain number is DHF.

Test item:

1. Determination of morphological characteristics of microbial strains;
2. Comparison with reference of 18S and rRNA gene sequences of microorganisms;
3. According to the above results, the classification status of microbial strains was preliminarily determined.

NOTE: The identification results only for samples; without consent, shall not be used for identification of the name of commercial publicity.

China Center for Type Culture Collection (CCTCC)

Attachment I: Bacteria strain identification report -- Morphological characteristics of microbial strains

1.DHF （Algae）

Detection result:

Figure 1. Microscope photographs of DHF

Figure 2. DHF Flat colony positive observation photograph

图 3. DHF Observations of flat colonies on the reverse side

Morphological character:

As can be seen from Fig. 1, globular vegetative cells undergo two mitotic propagation, which is an important morphological feature of *Schizochytrium*.

Appendix II : Strain identification report -- Determination and analysis of 18SrRNA sequences of microbial strains

1) DHF 18SrRNA sequence:

GTGTCGCCCTTTCCGCAGGTTCACCTACGGAAACCTTGTTACGACTTCACC
TTCCTCTAAACAATAAGATTCACCCGAGTTCTGCCTCTGTCCAAAAATCAAT
CCAAACAGAAACATCCCATGGTTTCATCGGACCGTTCAATCGGTAGGTGCG
ACGGGCGGTGTGTACAAAGGGCAGGGACGTATTCAATGCAAGCTGATGAC
TTGCGTTTACTAGGAATTCCTCGTTGGAGATTAATAATTGCAAAAATCTAGC
CCCAGCACGATGAGCGTTCCAAGGATTAGCCAGGCCTTCCGACCAAGCAC
TCAATTCCAAAAATGAAATTAAAACCCGATGAACCCATCAGTGTAGCGCGC
GTGCGGCCCAGAACATCTAAGGGCATCACAGACCTGTTATTGCCTCGAACT
TCCTGCCCGTAAACCGGACATGTCCCTCTAAGAAGTAAAAACGCACTATGT
TGCCATACCACGCACTATTTAGTAGGCCGAGGTCTCGTTCGTTAACGGAATT
AACCAGACAAATCACTCCACCAACTAAGAACGGCCATGCACCACCACCCA
TAGAATCATGAAAGAGCTCTCAATCTGTCAATCCTACCTATGTCTGGACCTG
GTAAGTTTTCCCGTGTTGAGTCAAATTAAGCCGCAGGCTCCACTCCTGGTG
GTGCCCTTCCGTCAATTCCTTTAAGTTTCAGCCTTGCGACCATACTCCCCCC
GGAACCCAAAGACTTTGATTTCTCATGTGCTGCTGCTGAGGCCCATAGAAT
AAAGCACCCAACAATCGCAAGTCGGCATCGTTTACGGTCTAGACTACGATG
GTATCTAATCATCTTCGATCCCCAGACTTTCGTTCTTGATTAATGAAAACATG
CTTGGTAAATGCCTTCGCTCTAGTTCGTCTTTCGGAAATCCAAGAATTTCAC
CTCTAGCTCCTAAATACGAATACCCCCAACTGTTCCTATTAACCATTACTCAG
GCGTGCAAACCAACAAAATAGCACCCAAGTCCTATCTTATCATCCCATAATA
AACATACCGGTCATACGACCTGCTTGGAACACTCTGCTTTGATTACAGTGA
AAGATTTCTCCCCTATAAAGAAAAGAAAAAGATGGCCAAGGCAACACAGA
CAATCAATCCCCATTCAGGGAAAGCACCGGTCGCCCATGCCAGAAATTCAA
CTACGAGCTTTTTAACCGCAACAACTTTAGCATATGCTTCTGGAGCTGGAAT
TACCGCGGCTGCTGGCACCAGACTTGCCCTCCAGTTGATCCTCGATGAGGG
TTTTACATTGCTCTCATTCCGATAGCAAAACGCATACACGCTTCGCATCGATA
TTTCTCGTCACTACCTCGTGGAGTCCACAGTGGGTAATTTACGCGCCTGCTG
CTATCCTTGGATATGGTAGCCGTCTCTCAGGCTCCCTCTCCGGAGTCGAGCC
CTAACTCTCCGTCACCCGTTATAGTCACCGTAGTCCAATACACTACCGTCGA
CAACTGATGGGGCAGAAACTCAAACGATTCATCGACTAAAATAGTCAATCT
GCTCAATTATCATGATTCACCAATAAAATCGGCTTCAATCTAATAAGTGCAG

CCCCATACAGGGCTCTGACAGCATGTATTATTTCCAGAATTACTGCAGGTAT
CCACATAAAAGAAACTACCGAAGAAATTATTACTGATATAATGAGCCGTTCG
CAGTCTCACAGTACAATCGCTTATACTTACACATGCATGGCTTAATCTTTGA
GACAAGCATATGACTACAAGGGCGACAC

2）DHF 18SrRNA sequencing, BLAST results：:

Accession	Description	Max score	Total score	Query cover	E value	Ident
JX847360.1	Schizochytrium sp. LY-2012 isolate PKU#Mn4 18S ribosomal RNA gene, partial sequence	3133	3133	94%	0	99%
JX847367.1	Schizochytrium sp. LY-2012 isolate PKU#Mn15 18S ribosomal RNA gene, partial sequence	3129	3129	94%	0	99%
HM042908.2	Schizochytrium limacinum isolate OUC168 18S ribosomal RNA gene, partial sequence	3129	3129	94%	0	99%
KF500513.1	Schizochytrium sp. SW1 18S ribosomal RNA gene, partial sequence	3121	3121	95%	0	99%
HM042909.2	Schizochytrium limacinum isolate OUC169 18S ribosomal RNA gene, partial sequence	3110	3110	94%	0	99%
HM042911.2	Schizochytrium limacinum isolate OUC175 18S ribosomal RNA gene, partial sequence	3105	3105	94%	0	99%
HM042912.2	Schizochytrium limacinum isolate OUC191 18S ribosomal RNA gene, partial sequence	3097	3097	94%	0	99%
HM042906.2	Schizochytrium limacinum isolate OUC109 18S ribosomal RNA gene, partial sequence	3094	3094	94%	0	99%

Conclusion:

According to the above test results, the 1 strains were identified as:

Strain **DHF**: ***Schizochytrium*** **sp. (裂殖壶菌属)**

_____ 止 _____

Appraiser(sign):

Person in charge（sign）:

中国典型培养物保藏中心
业务专用章
二〇一九年四月三日

NOTE： The identification results only for samples; without consent, shall not be used for identification of the name of commercial publicity.

Appendix C. Mutagenicity Study of DHA-Rich Oil

TOXICOLOGY STUDY REPORT

Title of Study	Mutagenicity Study of Hubei Fuxing's DHA -rich Oil
Study Number	M2019-T002
Entrustment Company	NutraSource, Inc.
Address of Entrustment Company	NutraSource, Inc., 6309 Morning Dew Ct, Clarksville, MD 21029
Contact Person	Susan Cho, Ph.D.
Contact Tel. and E-mail	+1-410-531-3336 (O); +1-301-875-6454 (C)
Primary Test Facility	School of Life Sciences, Yantai University
Address of Research Institute	30, Qingquan RD, Laishan District, Yantai, China
Contact Person	Yonglin Gao
Contact Tel. and E-mail	86-15854569558;gylbill@163.com; gaoyonglin@ytu.edu.cn.
Study Director	Yonglin Gao
Study Participants	Yonglin Gao *Coordinator* Meina Wang, Bing Han *Test products management*
Study Start and End Dates	Mar. 2019

ABSTRACT

As a part of a safety evaluation, we evaluated the potential mutagenicity of docosahexaenoic acid (DHA)-rich oil using a bacterial reverse mutation assay. Five strains of *Salmonella typhimurium* (TA97, TA98, TA100, TA102, and TA1535) were treated with DHA-rich oil at concentrations of 0 (solvent control), 100, 50, 15, and 12.5 μl/plate in the presence and absence of an exogenous metabolic activation system (S9) by the plate incorporation method. 4-Nitroquinoline (4-NQ), sodium azide (NaN_3), and mitomycin (MMC) were used as the positive controls in conditions without S9 mix. 2-Aminofluorene (2-AF), 1,8-dihydroxyanthraquinone (1,8-DT), and cyclophosphamide (CTX) were used as the positive controls in conditions with S9 mix. All plates were incubated at 37 °C for 72 h, and the number of revertant colonies was counted. No increase in revertant frequencies was found at any test doses (100, 50, 15, and 12.5 μl/plate) in any of the tester strains with or without S9 compared to those in the vehicle control cultures. The positive control chemicals for each tester strain induced obvious increases in the number of revertant colonies compared to the vehicle control. The data indicated that DHA-rich oil, up to 100 μl/plate (the maximum concentration), was non-mutagenic under the conditions used in this test.

Keywords: DHA-rich oil; Bacterial reverse mutation assay

1. Study design

As a part of a safety evaluation, we evaluated the potential mutagenicity of Hubei Fuxing's DHA-rich oil using a bacterial reverse mutation assay. The study was performed in accordance with FDA Redbook 2000: chapter IV.C.1.a Bacterial Reverse Mutation Test. The study was performed in accordance with Good Laboratory Practices (GLP) regulations.

1. Materials and methods

Five strains of *Salmonella typhimurium* (TA97, TA98, TA100, TA102, and TA1535) were treated using the plate incorporation method. We selected the concentrations for the test based on a preliminary study, and the results indicated that docosahexaenoic acid (DHA)-rich oil did not show any antibacterial activity up to the maximum concentration**,** 100 μl/plate. TA97, TA98, TA100, TA102, and TA1535 were treated with DHA-rich oil at concentrations of 0 (solvent control), 100, 50, 15, and 12.5 μl/plate in the presence and absence of an exogenous metabolic activation system (S9) by the plate incorporation method. We prepared triplicate plates for each concentration.

4-Nitroquinoline (4-NQ), sodium azide (NaN_3), and mitomycin (MMC) were used as the positive controls in conditions without S9 mix (Table 1). 2-Aminofluorene (2-AF), 1,8-dihydroxyanthraquinone (1,8-DT), and cyclophosphamide (CTX) were used as the positive controls in conditions with S9 mix (Table 1). All plates were incubated at 37 °C for 72 h, and the number of revertant colonies was counted.

Table 1. The positive control for study

Salmonella typhimurium	S9	Dose (μg/plate)
TA97	-S9	4-NQ (2.0)
	+S9	2-AF (60.0)
TA98	-S9	4-NQ (2.0)
	+S9	2-AF (60.0)
TA100	-S9	NaN_3 (1.5)
	+S9	2-AF (60.0)
TA102	-S9	MMC (1.0)
	+S9	1,8-DT (50)
TA1535	-S9	NaN_3 (1.5)
	+S9	CTX (200.0)

We declared the test substance mutagenic if the number of revertant colonies in the test dose was more than twofold than that in the control, or if the number of revertant colonies increased in a dose-dependent manner compared to the control in at least one strain with or without the metabolic activation system. The validity of the study was confirmed by more than twofold increase in the number of revertant colonies in the positive control plates compared to the control.

3. Statistical analysis

We used SPSS 11.5 software for Windows to perform all analyses. One-way ANOVA with Dunnet's post-hoc test was used to compare the treatment and control group data. A P-value less than 0.05 was considered statistically significant.

4. Results

The mutagenicity of DHA-rich oil in bacteria was evaluated up to a maximum dose of 100 μl/plate using the plate incorporation method (Tables 2 and 3). We found no increase in revertant frequencies at any test doses in any of the tester strains with or without S9 compared to those in the vehicle control cultures. The positive control chemicals for each tester strain induced obvious increases in the number of revertant colonies compared to the vehicle control. The data indicated that DHA-rich oil was non-mutagenic under the conditions used in this test.

5. Conclusion

Under our test conditions, a reverse mutation assay using five strains of *Salmonella typhimurium* (TA97, TA98, TA100, TA102, and TA1535), DHA-rich oil (100, 50, 15, and 12.5 μl/plate, respectively) did not increase the number of revertant colonies in any tester strains regardless of metabolic activation by S9 mix. The data indicated that DHA-rich oil was non-mutagenic under the conditions used in this test.

Table 2 Bacterial mutation assay results (- S9) [a]

Group	Dose	Mean revertant colony counts per plate				
		TA97	**TA98**	**TA100**	**TA102**	**TA1535**
Vehicle control	—	148.33±11.68	18.00±2.65	135.67±17.16	255.33±10.26	15.00±4.58
DHA-rich oil	100 μl/Plate	139.67±9.87	18.67±6.03	129.33±3.51	224.00±32.05	12.00±3.00
	50 μl/Plate	149.67±12.22	15.67±1.53	114.67±26.31	206.67±28.22	16.67±1.53
	25 μl/Plate	130.33±6.03	18.33±2.52	105.00±20.66	227.00±53.69	10.33±2.52
	12.5 μl/Plate	132.33±7.23	14.00±1.00	115.00±7.00	213.33±41.68	13.67±3.06
4-NQ	2.0 μg/Plate	1145.67±135.98**	1870.67±166.49**	—	—	—
NaN_3	1.5 μg/Plate	—	—	344.33±84.67**	—	346.33±87.51**
MMC	1.0 μg/Plate	—	—	—	1267.67±309.82**	—

Abbreviations: 4-NQ = 4-nitroquinoline; DAM = daunomycin; NaN_3 = sodium azide; MMC = Mitomycin.

[a] Values are the mean of triplicate plates. ** P<0.01, compared with vehicle control.

Table 3 Bacterial mutation assay results (+ S9) [a]

Group	Dose	Mean revertant colony counts per plate				
		TA97	TA98	TA100	TA102	TA1535
Vehicle control	—	133.33±22.19	19.33±4.73	118.67±6.66	205.33±30.57	10.67±2.31
DHA-rich oil	100 μl/Plate	133.00±19.31	14.67±2.08	119.00±13.75	186.00±29.46	9.33±2.52
	50 μl/Plate	160.00±11.53	23.33±1.15	116.33±15.04	206.00±13.23	14.00±3.00
	25 μl/Plate	140.00±11.53	16.00±3.61	107.33±21.20	202.67±19.35	11.33±3.21
	12.5 μl/Plate	147.33±15.28	15.33±0.58	101.67±20.01	265.33±41.00	10.67±0.58
2-AF	60.0 μg/Plate	1081.00±174.58**	1841.33±257.07**	1242.33±350.41**	—	—
1,8-DT	50.0 μg/Plate	—	—	—	524.00±125.30 **	—
CTX	200.0 μg/Plate	—	—	—	—	191.67±120.80 **

Abbreviations: 2-AF = 2-aminofluorene; 1,8-DT = 1,8-dihydroxyanthraquinone; CTX = cyclophosphamide.

[a] Values are the mean of triplicate plates.

** P<0.01, compared with vehicle control.

Appendix D. Oral Acute Toxicity Study of Hubei Fuxing's DHA-Rich Oil in Rats

TOXICOLOGY STUDY REPORT

Title of Study	Oral Acute Toxicity Study of Hubei Fuxing's DHA-rich Oil in Rats
Study Number	A2019-T002
Entrustment Company	NutraSource, Inc.
Address of Entrustment Company	NutraSource, Inc. 6309 Morning Dew Ct, Clarksville, MD 21029, USA
Contact PersonContact Person	Susan Cho, Ph.D., and Albert W. Lee
Contact Tel. and E-mail	+1-410-531-3336 (O) +1-301-875-6454 (C)
Primary Test Facility	School of Life Sciences, Yantai University
Address of Research Institute	30, Qingquan RD, Laishan District, Yantai, China
Contact Person	Yonglin Gao
Contact Tel. and E-mail	86-15854569558; gylbill@163.com; gaoyonglin@ytu.edu.cn.
Study Director	Yonglin Gao
Study Participants	Yonglin Gao, Shuqin Qu, Yiran Wang

Study Start and End Dates Feb. 2019-Mar. 2019

ABSTRACT

Docosahexaenoic acid (DHA), a 22-carbon fatty acid containing six double bonds, is a member of the omega-3 family of essential fatty acids. The aim of this study was to evaluate the acute toxicity of Hubei Fuxing's DHA-rich oil after oral administration in rats. The test substances were administered to young rats by oral gavage at doses of 0 (control), 0, 0.91, 1.82, or 3.64 g/kg body weight (bw) (or 1.0, 2.0, and 4.0 ml/kg bw; 5 males and 5 females per group). Animals were observed for 14 days to monitor changes in clinical signs (i.e., changes in eyes, mucous membranes, or behavior patterns; loss of fur or scabbing), body weight, and clinical signs, as well as food consumption. At the end of the study, animals were sacrificed, and major organs (such as liver, kidneys, spleen, heart, and lungs) were examined macroscopically and microscopically if needed. No animal died during the 14-day observation period, and no clinical signs of abnormality were observed at any dose level. Furthermore, no significant differences in mean body weight, food consumption, and organ weights were found among the four test and control groups. No treatment-related abnormalities were observed in the macroscopic examinations. In summary, the acute oral LD_{50} for Hubei Fuxing's DHA-rich oil was above 3.64 g/kg bw (or 4.0 ml/kg bw, the maximum dose volume) in both male and female rats.

Key words: DHA-rich oil; Acute toxicity study; Rat

METHODS

2. Study design

The study was performed in accordance with the Food and Drug Administration (FDA) Redbook 2000: chapter IV.C.3.a Short-Term Toxicity Studies with Rodents. Docosahexaenoic acid (DHA)-rich oil was administered by gavage to rats (0, 1.0 ml/kg bw, 2.0 ml/kg bw, and 4.0 ml/kg bw; or 0, 0.91, 1.82, or 3.64 g/kg bw; 5 males and 5 females for each group) and observed for 14 days. Clinical signs, body weight, food consumption, and death rates were observed. On day 15, all surviving animals were sacrificed and organs were weighed, including lungs, heart, kidneys, liver, and spleens. The study was performed in accordance with Good Laboratory Practices (GLP) regulations.

2. Animals

Sprague-Dawley rats, 6 weeks of age, were housed in cages under hygienic conditions and placed in a controlled environment with a 12-h light/dark cycle at 23±3 °C and 40-60% humidity. Animals were allowed a commercial standard rat cube diet and water *ad libitum*. All procedures involving the use of laboratory animals were in accordance with the Guidelines of the Animal Care.

3. Treatment

Based on stratified randomization by body weights taken before treatment, rats were divided into five groups (each group of 10 rats consisted of 5 male and 5 female rats): control, 0.91, 1.82, or 3.64 g/kg bw DHA-rich oil (orally administered dose by gavage). Group assignments are outlined in Table 1.

Table 1. Experimental design of a 14-day rat acute toxicity study.

Groups	Test substance g/kg bw DHA-rich oil	Number of animals
1	0 (Control)	**10（♀:5+♂:5）**
2	0.91	**10（♀:5+♂:5）**
3	1.82	**10（♀:5+♂:5）**
4	3.64	**10（♀:5+♂:5）**

4. Observations and clinical tests

All animals were observed twice daily for clinical signs of toxicity, mortality, and morbidity. The body weight of each rat was measured pre-test, weekly thereafter, and at

sacrifice. Food consumption also was noted.

5. Organ weights, gross necropsy, and histopathological examinations

At the end of treatment, all surviving animals were fasted overnight. The body weight and the main organ weights, including liver, kidneys, spleen, heart, and lungs, were measured. Moreover, the coefficient was reported as the organ/body weight ratio. These tissues were examined, and gross lesions were examined microscopically. If treatment-related effects were noted in certain tissues, they were examined microscopically.

6. Statistical analysis

We used SPSS 11.5 software for Windows to perform all analyses. One-way ANOVA with Dunnet's post-hoc test was used to compare the test and control group data. A P-value less than 0.05 was considered statistically significant.

RESULTS

1 General clinical signs and mortality

All rats survived to the end of the experiment and appeared healthy throughout the study period. No obvious abnormal clinical signs (i.e., changes in eyes, mucous membranes, or behavior patterns; loss of fur or scabbing) were observed in all groups. As shown in Tables 2 and 3, there were no significant differences in body weight between the DHA-rich oil treated groups and the control group.

2 Food consumption

In the experiment, food consumption was studied in rats during the 14-day study. The results showed that all data were within historic controls obtained in our facility. There were also no significant differences in food consumption (Tables 4 and 5) between the DHA-rich oil treated groups and the control group.

3 The organ/body weight ratio (the organ coefficient)

The organ/body weight ratios (the organ coefficient) are shown in Tables 6 and 7. No consistent, statistically significant, or dose-dependent adverse effects were observed in all groups. In the macroscopic examination, there are no treatment-related effects noted in these tissues.

CONCLUSION

Under our test conditions, the acute oral LD_{50} for Hubei Fuxing's DHA-rich oil was above 3.64 g/kg bw (or 4.0 ml/kg bw, the maximum dose volume) in both male and female rats.

DHA-Rich Oil (Hubei Fuxing)

Table 2. Body weight change of female rats during a 14-day study (g)

Groups	Test substance g/kg bw DHA-rich oil	Before	1st week	2nd week
1	0 (Control)	99.6±1.8	138.0±4.8	164.6±8.2
2	0.91	100.6±2.4	140.8±10.8	166.2±5.8
3	1.82	98.8±1.8	138.4±6.0	169.2±8.4
4	3.64	100.8±2.8	137.0±3.3	163.4±7.9

Table 3. Body weight change of male rats during a 14-day study (g)

Groups	Test substance g/kg bw DHA-rich oil	Before	1st week	2nd week
1	0 (Control)	104.8±3.8	148.2±4.7	204.0±5.0
2	0.91	103.0±4.3	150.20±7.3	206.6±8.3
3	1.82	102.6±4.0	151.4±9.5	210.6±7.8
4	3.64	103.80±3.3	149.6±6.1	203.2±5.8

Table 4. Food consumption of female rats during a 14-day study (g/100 g bw/day)

Groups	Test substance g/kg bw DHA-rich oil	1st week	2nd week
1	0 (Control)	12.0±1.0	11.3±1.1
2	0.91	12.1±1.9	11.52±1.7
3	1.82	12.1±1.6	11.82±0.7
4	3.64 g/kg	12.3±1.8	12.0±0.8

Table 5. Food consumption of male rats during a 14-day study (g/100 g bw/day)

Groups	Test substance g/kg bw DHA-rich oil	1st week	2nd week
1	0 (Control)	11.8±1.4	11.4±0.5
2	0.91	11.8±1.1	11.19±0.8
3	1.82	11.7±1.3	10.87±0.7
4	3.64	12.0±1.8	11.13±1.1

DHA-Rich Oil (Hubei Fuxing)

Table 6. The organ coefficient of female rats after a 14-day study (% bw)

	0 (Control)	0.91 g/kg bw DHA-rich oil	1.82 g/kg bw DHA-rich oil	3.64 g/kg bw DHA-rich oil
Heart	0.42±0.04	0.44±0.07	0.37±0.06	0.42±0.06
Liver	3.79±0.52	3.69±0.26	3.83±0.33	3.56±0.21
Spleen	0.29±0.03	0.31±0.05	0.30±0.04	0.28±0.05
Lung	0.61±0.04	0.61±0.02	0.61±0.05	0.60±0.06
Kidney	0.93±0.08	0.98±0.09	0.95±0.07	0.95±0.09

Abbreviations: bw = Body weight; DHA = Docosahexaenoic acid.

Table 7. The organ coefficient of male rats after a 14-day study (% bw)

	0 (Control)	0.91 g/kg bw DHA-rich oil	1.82 g/kg bw DHA-rich oil	3.64 g/kg bw DHA-rich oil
Heart	0.39±0.03	0.40±0.03	0.40±0.05	0.41±0.03
Liver	3.47±0.11	3.52±0.25	3.51±0.17	3.58±0.22
Spleen	0.34±0.09	0.31±0.02	0.32±0.05	0.32±0.02
Lung	0.49±0.05	0.46±0.05	0.45±0.04	0.47±0.04
Kidney	0.95±0.04	0.92±0.08	0.90±0.06	0.97±0.02

Abbreviations: bw = Body weight; DHA = Docosahexaenoic acid.

Appendix E. Expert Panel Consensus Statement

Introduction

Hubei Fuxing Biotechnology ("Hubei Fuxing") convened a panel of independent scientists (the "Expert Panel"), qualified by their scientific training and relevant national and international experience to evaluate the safety of food ingredients, to conduct a critical and comprehensive evaluation of the available pertinent data and information on docosahexaenoic acid (DHA) and to determine whether the proposed uses in food would be Generally Recognized as Safe (GRAS) based on scientific procedures. The Expert Panel consisted of the following qualified experts: Michael Falk, Ph.D. (LSRO solutions, LLC), George C. Fahey, Ph.D. (Professor Emeritus, The University of Illinois-Urbana Champaign), and Joanne Slavin, Ph.D., R.D. (Professor, The University of Minnesota). Susan S. Cho, Ph.D. (NutraSource, Inc.) served as the technical advisor to the Expert Panel.

The Expert Panel, independently and collectively, critically evaluated a comprehensive package of scientific information and data compiled from the literature. The information was presented in a dossier produced by NutraSource, Inc. ("The Generally Recognized As Safe [GRAS] Determination of Docosahexaenoic acid [DHA]-Rich Oil as a Food Ingredient"). The Expert Panel evaluated other information deemed appropriate or necessary. To the best of our knowledge, this determination is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to us and pertinent to the evaluation of the safety and GRAS status for the uses of this ingredient in food.

Common Knowledge Element of the GRAS Determination

The first common knowledge element for a GRAS determination is that data and information relied upon to establish safety must be generally available through published, peer reviewed scientific papers related to the safety assessment. These scientific articles include published preclinical studies and human clinical studies as well as scientific review articles. The second common knowledge element required for a GRAS determination is consensus among qualified scientists that the safety of the proposed uses of the substance has been demonstrated. Numerous GRAS notifications were submitted to the U.S. FDA regarding the use of DHA as an ingredient in infant formulas and selected conventional foods. GRAS notifications for infant formula applications include GRNs 553, 677, 731, 776, and 777 (FDA, 2015, 2017, 2018a, 2018c, and 2018d) and those for selected conventional food applications include GRNs 137, 732, 836, 843, and 844 (FDA, 2004, 2018b, 2019a, 2019b, and 2019c). These notifications all received 'no question' letters from the U.S. FDA.

The Expert Panel agrees that there are adequate data in the scientific literature to conclude that DHA is a common component of infant formulas, that various DHA-rich oils have been reviewed and approved as food ingredients for human use by the U.S. FDA and other expert

panels, and that the weight of the available evidence demonstrates that the proposed uses are safe.

Technical Element of the GRAS Determination

Docosahexaenoic acid (DHA) is a long-chain polyunsaturated fatty acids (LCPUFA) that is a primary structural component of the human brain, retina, and other tissues. DHA's structure is a 22-carbon chain carboxylic acid with six *cis*-double bonds; the first double bond is located at the third carbon from the omega end (methyl terminus). Thus, it is classified as an omega-3 fatty acid. It can be obtained directly from maternal milk, algal oil, or fish oil.

Hubei Fuxing intends to market DHA-rich oil as an ingredient in exempt (pre-term and/or low birth weight infants; amino acid- and/or extensively hydrolyzed protein-based) and non-exempt infant formulas (term infants; soy-, whey-, and/or milk-based; ages from birth to 12 months) in combination with a safe and suitable source of arachidonic acid (ARA). The maximum use level will be 0.5% of total fat as DHA. This level corresponds to a maximum use level of 1.39% of dietary fat as DHA-rich oil because it has ≥36% DHA. The ratio of DHA to ARA would range from 1:1 to 1:2. Hubei Fuxing intends for DHA-rich oil, produced from *Schizochytrium* sp., to be used as a food ingredient. Hubei Fuxing's DHA-rich oil will be added to ready-to-drink or powder form of infant formulas from which reconstituted infant formulas can be prepared. The intended use level is similar to all other approved uses for incorporation of DHA or DHA-rich oil in infant formula (GRNs 553, 677, 731, 776, and 777). In addition, Hubei Fuxing intends for DHA-rich oil (containing ≥36% DHA) to be used in the same food categories as those listed in GRNs 137 and 732 and in 21 CFR 184.1472(a)(3) (menhaden oil), except in egg, meat, poultry, and fish products, at maximum use levels that are 27.78% of those specified in 21 CFR 184.1472(a)(3), which was finalized in 2005 (FDA, 2005).

Hubei Fuxing's DHA is produced by a fermentative process using non-toxigenic, non-pathogenic *Schizochytrium* sp. DHF. All raw materials and processing aids used in the fermentation and manufacturing processes are food grade. Hubei Fuxing observes the principles of Hazard Analysis Critical Control Point (HACCP)-controlled manufacturing process and current good manufacturing practices (cGMP) and rigorously tests its final production batches to verify adherence to quality control specifications. Based on certificates of analysis (COAs), the Expert Panel concluded that the manufacturing process is producing DHA that meets specifications for chemical identity, fatty acid profile, and contaminants (heavy metals and microorganisms).

The bioequivalence of two types of algal DHA-rich oils (derived from either *Crypthecodinium cohnii* [DHASCO®] or *Schizochytrium* sp. [DHASCO-B®]) was demonstrated in preweaning farm piglets and in humans when administered in a blend with ARA oil (Fedorova-Dahms et al., 2014; Yeiser et al., 2016).

The DHA content of Hubei Fuxing's DHA-rich oil is at least 36% by weight, comparable to concentrations described in the previous GRAS notices (GRNs 137, 553, 677, and 731) which are acknowledged as GRAS by the FDA. The fatty acid profile of Hubei Fuxing's DHA-rich oil is substantially equivalent to that described in GRN 677 and in the studies by Schmidt et al. (2012a, 2012b).

DHA-rich oil and DHA-rich microalgae (DRM) have been evaluated by *in vitro* and *in vivo* genotoxicity studies, subchronic toxicity studies in rats with and without *in utero* phase, maternal and developmental toxicity in rats and rabbits, and reproductive and developmental toxicity in rats. DHA was reported as non-mutagenic and non-clastogenic in all studies conducted. For DHA-rich oils, the No Observed Adverse Effect Level (NOAEL), established from subchronic toxicity studies, ranged from 3,149 to 5,000 mg/kg bw/day in rats (Fedorova-Dahms et al., 2011a; Lewis et al., 2016; Schmitt et al., 2012a). From reproductive and developmental toxicity studies of DHA-rich oils, the NOAELs for F_0 were found to range from 2,000 (Schmitt et al., 2012b) to 8,322 mg/kg bw/day (F_0 females during lactation) in rats (Fedorova-Dahms et al., 2011b). In subchronic toxicity studies with an *in utero* exposure phase, the NOAELs for F_1 ranged from 3,526 (males - Schmitt et al., 2012b) to 4,399 mg/kg bw/day (females - Fedorova-Dahms et al., 2011b) in rats.

However, in a reproductive and developmental toxicity study in rabbits by Hammond et al. (2001), both the high-dose (1,800 mg/kg/day) DRM and fish oil control groups experienced marked and sustained reduction in food consumption during the prenatal period and a slight increase in abortions. The NOAELs were determined to be 600 mg/kg bw/day for maternal toxicity and 1,800 mg/kg bw/day, the highest level tested, for developmental toxicity in rabbits (corresponding to 130 mg DHA-rich oil/kg bw/day for maternal toxicity and 392 mg DHA-rich oil/kg bw/day for developmental toxicity). However, the authors noted that abortions occurred spontaneously more frequently in rabbits than in other commonly used laboratory species and that the incidences of abortions in both the high-dose DRM and fish oil control groups fell within historical limits for the laboratory.

On the basis of these findings, the Expert Panel for the safety evaluation of Hubei Fuxing's DHA-rich oil concluded that NOAEL of 3,149 mg DHA-rich oil/kg bw/day in rats was an appropriate basis for a determination of safety.

Human clinical studies reported daily doses of DHA instead of DHA-rich oils. In adults, daily doses of up to 2 g DHA from algal sources were not associated with treatment-related adverse effects on the measured outcomes in select subjects (Molfino et al., 2017, 2019; Smith et al., 2018; MacDonald and Sieving, 2018).

A study by Devlin et al. (2017) reported no adverse effects of DHA on cognitive development when toddlers aged 13.4 months were randomized to receive DHA (200 mg/day; *Schizochytrium* source) and ARA (200 mg/day) (supplement) or a corn oil (control) until age 24 months.

Prenatal exposure studies employed 600 to 800 mg algal DHA supplementation during pregnancy. No adverse effects on infant development, anthropometric measurements, cognitive performance, verbal and language skills, brain white and gray matter volumes, and/or RBC concentrations of DHA were reported for mothers and offspring up to 6 years of age (Carlson et al., 2018; Colombo et al., 2019; Foster et al., 2017; Hidaka et al., 2018; Kerling et al., 2019).

From the DHA Intake and Measurement of Neural Development (DIAMOND) study, which employed up to 0.96% total fatty acids as DHA with a fixed concentration of ARA (0.64% of total fatty acids as ARA), Colombo et al. (2017) and Lepping et al. (2019) reported that algal DHA (plus ARA) supplementation in the first year of life had no adverse effects on cognitive performance, brain region spontaneous function, brain volume in various regions of the brain, and/or RBC concentrations of DHA at the time of follow-up for up to 9 years. The DHA concentrations tested in these studies were up to 51 - 61 mg DHA/kg bw/day. Between June 2017 and December 2019, no new preterm infant studies with algal DHA were published. Previous GRAS notices reviewed the studies by Almaas et al. (2015, 2016) that reported no adverse effects of DHA when human milk supplemented with 32 mg DHA (0.86% of total fatty acids as DHA; source not specified) and 31 mg ARA (0.91% of total fatty acids as ARA) per 100 mL was fed to preterm infants each day for 9 weeks after birth with an 8-year follow-up.

Based on the substantial equivalence of Hubei Fuxing's DHA-rich oil to other algal DHA-rich oils whose safety has already been established, the intended use levels commensurate with safe dose levels tested in human clinical studies, animal toxicology studies and mutagenicity and genotoxicity studies on various DHA-rich oils, and the history of safe use in humans, the Expert Panel concluded that Hubei Fuxing's intended use of its DHA-rich oil in term and preterm infant formulas and selected conventional foods is safe.

Conclusion

We, the undersigned members of the Expert Panel, have individually, collectively, and critically evaluated the materials summarized above on the safety of Hubei Fuxing's DHA-rich oil and other information deemed appropriate and unanimously conclude that Hubei Fuxing's DHA-rich oil, manufactured as described in the dossier and consistent with cGMP, and meeting appropriate food grade specifications, is Generally Recognized As Safe (GRAS) based on scientific procedures for use as an ingredient in term and preterm infant formulas and selected conventional foods at levels specified in the accompanying dossier. It is our opinion that other qualified and competent scientists reviewing the same publicly available information would reach the same conclusions.

Expert Panel Members:

[redacted] 03/13/20

Michael Falk, Ph.D. Date
LSRO Solutions, Rockville, MD

[redacted] 3/16/20

George C. Fahey, Jr., Ph.D. Date
Professor Emeritus, University of Illinois, Urbana, IL

[redacted] 3/17/20

Joanne Slavin, Ph.D., R.D. Date
Professor, University of Minnesota, St. Paul, MN

Technical Advisor to the Expert Panel:

[redacted] 3/20/2020

Susan Cho, Ph.D. Date
NutraSource, Inc., Clarksville, MD 21029

References

Almaas AN, Tamnes CK, Nakstad B, Henriksen C, Walhovd KB, Fjell AM, Due-Tønnessen P, Drevon CA, Iversen PO. Long-chain polyunsaturated fatty acids and cognition in VLBW infants at 8 years: an RCT. Pediatrics. 2015;135:972-80.

Almaas AN, Tamnes CK, Nakstad B, Henriksen C, Grydeland H, Walhovd KB, Fjell AM, Iversen PO, Drevon CA. Diffusion tensor imaging and behavior in premature infants at 8 years of age, a randomized controlled trial with long-chain polyunsaturated fatty acids. Early Hum Dev. 2016;95:41-6.

Carlson SE, Gajewski BJ, Alhayek S, Colombo J, Kerling EH, Gustafson KM. Dose-response relationship between docosahexaenoic acid (DHA) intake and lower rates of early preterm birth, low birth weight and very low birth weight. Prostaglandins Leukot Essent Fatty Acids. 2018;138:1-5.

Colombo J, Jill Shaddy D, Kerling EH, Gustafson KM, Carlson SE. Docosahexaenoic acid (DHA) and arachidonic acid (ARA) balance in developmental outcomes. Prostaglandins Leukot Essent Fatty Acids. 2017;121:52-6.

Colombo J, Shaddy DJ, Gustafson K, Gajewski BJ, Thodosoff JM, Kerling E, Carlson SE. The Kansas University DHA Outcomes Study (KUDOS) clinical trial: long-term behavioral follow-up of the effects of prenatal DHA supplementation. Am J Clin Nutr. 2019;109:1380-1392.

Devlin AM, Chau CMY, Dyer R, Matheson J, McCarthy D, Yurko-Mauro K, Innis SM, Grunau RE. Developmental outcomes at 24 months of age in toddlers supplemented with arachidonic acid and docosahexaenoic acid: Results of a double blind randomized, controlled trial. Nutrients. 2017;9(9).

Food and Drug Administration (FDA). 2004. Agency Response Letter. GRAS Notice No. GRN000137. Algal oil (Schizochytrium sp.). February 12, 2004. http://www.fda.gov/Food/FoodIngredientsPackanina/GenerallyRecognizedasSafeGRAS/GRAS Listingducm 153961.htm.

FDA. 2005. 21CFR 184.1472. Menhaden oil final rule (21 CFR, Part 184, Fed Reg (U.S.) 70 (55):14530-2.

FDA. 2015. Agency Response Letter. GRAS Notice No. GRN000553. Algal oil (40% docosahexaenoic acid) derived from *Schizochytrium* sp. June 19, 2015. https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm462744.htm.

FDA. 2017. Agency Response Letter. GRAS Notice No. GRN000677. Docosahexaenoic acid oil produced in *Schizochytrium* sp. May 2, 2017. https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM566347.pdf.

FDA. 2018a. Agency Response Letter. GRAS Notice No. GRN000731. Docosahexaenoic acid oil produced in *Schizochytrium* sp. April 6, 2018. https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM630673.pdf.

FDA. 2018b. Agency Response Letter. GRAS Notice No. GRN 000732. Docosahexaenoic acid oil produced in *Schizochytrium* sp. April 6, 2018. https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM630674.pdf.

FDA. 2018c. Agency Response Letter. GRAS Notice No. GRN000776. Algal oil (35% docosahexaenoic acid) from *Schizochytrium* sp. strain FCC-1324. October 26, 2018. https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm625983.pdf.

FDA. 2018d. Agency Response Letter. GRAS Notice No. GRN000777. Algal oil (55% docosahexaenoic acid) from *Schizochytrium* sp. strain FCC-3204. October 26, 2018. https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm625998.pdf

FDA, 2019a. Agency Response Letter. GRAS Notice No. GRN000836. Algal oil (50-60% docosahexaenoic acid) from *Schizochytrium* sp. HS01. Sep 3, 2019. https://www.fda.gov/media/132031/download.

FDA, 2019b. Agency Response Letter. GRAS Notice No. GRN000843. Algal oil (35% docosahexaenoic acid) from *Schizochytrium* sp. strain FCC-1324. Oct 18, 2019. https://www.fda.gov/media/133204/download.

FDA, 2019c. Agency Response Letter. GRAS Notice No. GRN000844. Algal oil (55% docosahexaenoic acid) from *Schizochytrium* sp. strain FCC-3204. Oct 18, 2019. https://www.fda.gov/media/133205/download.

Fedorova-Dahms I, Marone PA, Bailey-Hall E, Ryan AS. Safety evaluation of algal oil from *Schizochytrium* sp. Food Chem Toxicol. 2011a;49:70-7.

Fedorova-Dahms I, Marone PA, Bauter M, Ryan AS. Safety evaluation of DHA-rich algal oil from *Schizochytrium* sp. Food Chem Toxicol. 2011b;49:3310-8.

Fedorova-Dahms I, Thorsrud BA, Bailey E, Salem N Jr. A 3-week dietary bioequivalence study in preweaning farm piglets of two sources of docosahexaenoic acid produced from two different organisms. Food Chem Toxicol. 2014;65:43-51.

Foster BA, Escaname E, Powell TL, Larsen B, Siddiqui SK, Menchaca J, Aquino C, Ramamurthy R, Hale DE. Randomized controlled trial of DHA supplementation during pregnancy: Child adiposity outcomes. Nutrients. 2017;9.

Hammond BG, Mayhew DA, Holson JF, Nemec MD, Mast RW, Sander WJ. Safety assessment of DHA-rich microalgae from *Schizochytrium* sp. II. Developmental toxicity evaluation in rats and Rabbits. Regul Toxicol Pharmacol. 2001;33:205-17.

Hidaka BH, Thodosoff JM, Kerling EH, Hull HR, Colombo J, Carlson SE. Intrauterine DHA exposure and child body composition at 5 y: exploratory analysis of a randomized controlled trial of prenatal DHA supplementation. Am J Clin Nutr. 2018;107:35-42.

Kerling EH, Hilton JM, Thodosoff JM, Wick J, Colombo J, Carlson SE. Effect of prenatal docosahexaenoic acid supplementation on blood pressure in children with overweight condition or obesity: A secondary analysis of a randomized clinical trial. JAMA Netw Open. 2019;2(2):e190088.

Lepping RJ, Honea RA, Martin LE, Liao K, Choi IY, Lee P, Papa VB, Brooks WM, Shaddy DJ, Carlson SE, Colombo J, Gustafson KM. Long-chain polyunsaturated fatty acid supplementation in the first year of life affects brain function, structure, and metabolism at age nine years. Dev Psychobiol. 2019;61:5-16.

Lewis KD, Huang W, Zheng X, Jiang Y, Feldman RS, Falk MC. Toxicological evaluation of arachidonic acid (ARA)-rich oil and docosahexaenoic acid (DHA)-rich oil. Food Chem Toxicol. 2016;96:133-44.

MacDonald IM, Sieving PA. Investigation of the effect of dietary docosahexaenoic acid (DHA) supplementation on macular function in subjects with autosomal recessive Stargardt macular dystrophy. Ophthalmic Genet. 2018;39(4):477-486.

Molfino A, Amabile MI, Mazzucco S, Biolo G, Farcomeni A, Ramaccini C, Antonaroli S, Monti M, Muscaritoli M. Effect of oral docosahexaenoic acid (DHA) supplementation on DHA levels and omega-3 index in red blood cell membranes of breast cancer patients. Front Physiol. 2017;8:549.

Molfino A, Amabile MI, Lionetto L, Spagnoli A, Ramaccini C, De Luca A, Simmaco M, Monti M, Muscaritoli M. DHA oral supplementation modulates serum epoxydocosapentaenoic acid (EDP) levels in breast cancer patients. Oxid Med Cell Longev. 2019:1280987. doi: 10.1155/2019/1280987. eCollection 2019.

Schmitt D, Tran N, Peach J, Bauter M, Marone P. Toxicologic evaluation of DHA-rich algal oil: Genotoxicity, acute and subchronic toxicity in rats. Food Chem Toxicol. 2012a;50:3567-76.

Schmitt D, Tran N, Peach J, Edwards T, Greeley M. Toxicologic evaluations of DHA-rich algal oil in rats: Developmental toxicity study and 3-month dietary toxicity study with an *in utero* exposure phase. Food Chem Toxicol. 2012b;50:4149-57.

Smith DJ, Sarris J, Dowling N, O'Connor M, Ng CH. Adjunctive low-dose docosahexaenoic acid (DHA) for major depression: An open-label pilot trial. Nutr Neurosci. 2018;21:224-8.

Yeiser M, Harris CL, Kirchoff AL, Patterson AC, Wampler JL, Zissman EN, Berseth CL. Growth and tolerance of infants fed formula with a new algal source of docosahexaenoic acid: Double-blind, randomized, controlled trial. Prostaglandins Leukot Essent Fatty Acids. 2016;115:89-96.

From:	Susan S Cho
To:	Morissette, Rachel
Subject:	Re: questions for GRN 000933
Date:	Tuesday, October 6, 2020 2:56:50 PM
Attachments:	image001.png GRN933 Response to FDA Questions Final sent to FDA 10-6-2020 (1).pdf

---

Dear Dr. Morissette,

Please see Hubei Fuxing's response to FDA questions in the attached document. We hope we answered FDA questions properly. If you need further clarifications, please contact me. Thank you. Please stay healthy during this pandemic!

Sincerely,
Susan
Susan Cho, Ph.D.
NutraSource, Inc.
+1-410-531-3336 (O) +1-301-875-6454 (C)

On Wednesday, September 23, 2020, 12:46:39 PM EDT, Morissette, Rachel <rachel.morissette@fda.hhs.gov> wrote:

Dear Dr. Cho,

Please see attached our questions for GRN 000933.

Best regards,

Rachel

Rachel Morissette, Ph.D.
Regulatory Review Scientist

Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
rachel.morissette@fda.hhs.gov

October 6, 2020

To: Dr. Rachel Morissette

Subject: Response to FDA questions related to GRN 933, algal oil (≥36% docosahexaenoic acid) from *Schizochytrium* sp. strain "DHF" (algal oil (≥36% DHA))

From: Susan Cho, NutraSource, Inc. (new company name, AceOne RS)

Dear Dr. Morissette,

On behalf of Hubei Fuxing, we have prepared our response to FDA questions as follows.

Regulatory:

1. In Table 4 on page 13 of the notice, "yeast extract" is listed for 21 CFR 172.896. This regulation is for the intended use of "dried yeasts." 21 CFR 184.1983 is for the intended use of "bakers yeast extract." Please clarify which regulation is intended here.

   Hubei Fuxing's Response
   We confirmed with Hubei Fuxing that they are using baker's yeast extract. Thus, we have amended Table 4 as follows:

   Table 4. Raw Materials Used in Fermentation

Ingredient	Regulatory status
Yeast extract	21 CFR 184.1983
Glucose	21 CFR 168.110; 184.1857
Magnesium sulfate (heptahydrate)	21 CFR 184.1443
Potassium dihydrogen phosphate	No CFR citation *
Sodium chloride	21 CFR 182.1(a)
Calcium chloride	21 CFR 184.1193
Sodium hydroxide	21 CFR 184.1763

2. In Table 4 on page 13 of the notice, the footnote for "potassium dihydrogen phosphate" states that "FDA did not object to the substitution of K for Na for potassium chloride and potassium sulfate. Sodium phosphate-21 CFR 182.1778." Please provide a reference for this statement.

   Hubei Fuxing's Response
   We are withdrawing this statement. The amended Table 4 now does not have such a footnote.

3. On page 26 of the notice, Hubei Fuxing states "In accordance with 21 CFR 184.1(b)(2), the ingredient may be used in food to ensure that the total intake of EPA or DHA does not exceed 3.0 grams/person/day (FDA, 2005)." Please clarify if the regulation for menhaden oil (21 CFR 184.1472) is intended here instead.

   Hubei Fuxing's Response
   We think the regulation for menhaden oil (21 CFR 184.1472) is more appropriate; thus, we are changing the reference to 21 CFR 184.1472. It now reads as follows: "In accordance with 21 CFR 184.1(b)(2), the ingredient may be used in food to ensure that the total intake of EPA or DHA does not exceed 3.0 grams/person/day (21 CFR 184.1472)."

Chemistry:

4. In the notice, Hubei Fuxing mentions that DHA is a structural component of human tissues and that it may be obtained directly from maternal milk, algal oil, and fish oil. However, algal oil is composed of more than just DHA. Because the notice focuses on comparing the algal oil to previously reviewed algal oils, Hubei Fuxing does not discuss the algal oil and its components in context of the total diet. Please provide a statement about whether the fatty acids (not just DHA) and sterols/stanols that are present in the algal oil (≥36% DHA) are common to the diet from other food sources.

   Hubei Fuxing's Response
   We have added the following sentence: "Fatty acids (not just DHA) and sterols/stanols that are present in the algal oil (≥36% DHA) are common to the diet from other food sources."

5. On page 13 in Table 5 of the notice, the regulation listed for "protease enzyme preparation" is 21 CFR 184.1027. This regulation is for a very specific enzyme preparation of a mixed carbohydrase and protease enzyme product that includes carbohydrase and protease activity obtained from fermentation of a nonpathogenic strain of B. licheniformis. Novozyme's alcalase is listed in their marketing materials as a serine endo-peptidase from B. licheniformis. Therefore, while Novozyme's alcalase is from the same source microorganism as in 21 CFR 184.1027, it is not clear if Novozyme's alcalase includes both carbohydrase and protease activity to qualify under the regulation. Please clarify the identity of this enzyme preparation and how it is authorized for use, whether through a food additive regulation or through a GRAS conclusion.

   Hubei Fuxing's Response

The use of Novozyme's alcalase is authorized through a GRAS conclusion (GRN000564). In addition, this enzyme is subjected to 21 CFR 184.1150 for bacterially-derived protease enzyme preparation.

6. Regarding the filtration step in the manufacturing process, please address whether the filtration aid is safe and suitable for use in processing oils in the U.S., such as by citing an effective Food Contact Notification or food additive regulation for the filtration material.

Hubei Fuxing's Response

Hubei Fuxing uses micro-filtration to remove cell debris and other large molecules. Those filtration aids are subject to 21 CFR 177.2550.

7. Hubei Fuxing provides an implied rationale for looking at shellfish toxins and states that organic contaminates are not expected. Further, they provide data for mycotoxins but do not explain why they are looking for them. Please provide a brief statement explaining why Hubei Fuxing is testing for mycotoxins.

Hubei Fuxing's Response

Hubei Fuxing regularly monitors mycotoxins levels for all of its oil ingredients, such as DHA-rich oil and arachidonic acid-rich oil, as part of its quality control process. In addition, both DHA- and ARA-rich oil are directly consumed as a food additives under the Chinese food additive regulations that set strict limits on mycotoxins.

8. There are errors in how the notifier displays the data for the sterols/stanols in Table 12 on page 24 of the notice. 1) For example, cholesterol and a few other sterols are not included in total sterol/stanol value for GRN 000933 but are included in the total sterols for GRN 000533. 2) In addition, unidentified sterols for GRN 000933 are listed on a different line than for GRNs 000553 and 000677. These errors should be corrected, and the discussion about 3) why Hubei Fuxing considers the sterol/stanol levels to be comparable should be updated.

Hubei Fuxing's Response

We have eliminated the category 'others' for GRNs 000553 and 000677and integrated that information into new categories in Table12. In addition, we have revised the total plant sterols and stanols content of Hubei Fuxing's DHA-rich oil from 0.31 wt% to 0.48 wt%. Now it reads as follows: "Table 12 summarizes the total concentrations of plant sterols and plant stanols (0.48 wt% in fat) in Hubei Fuxing's DHA-rich oil. This level is comparable to the average total sterol values calculated from the values reported in GRN 000553 (0.54 wt%) and GRN 000677 (0.15 wt%), although sterol profiles may have some variations." Please see the revised Table 12 below:

Table 12. Comparison of Plant Sterols/Stanols in DHA-Rich Oils

Parameters, wt%	Current Notice	GRN 553*	GRN 677*
24-Methylenecholesterol	NR	0.0080	0.0064
24-Methylenecycloartanol	0.0028	NR	NR
Brassicasterol	0.0128	0.0070	<0.0045
Campestanol	0.0022	0.0005	<0.0002
Campesterol	0.0096	0.0097	0.0035
Cholesterol	0.1852	0.0664	0.0345
Citrostadienol	0.0015	NR	NR
Clerosterol	NR	0.0086	0.0188
Cycloartenol	0.00225	NR	NR
Delta-7-avenasterol	0.0052	0.0049	0.0065
Delta-5-avenasterol	NR	0.0095	0.0045
Delta-7-campersterol	NR	0.0024	<0.0044
Delta-7-stigmastenol	0.0212	0.0103	<0.0129
Delta-5,23-stigmastadienol	NR	0.0045	<0.0077
Delta-5,24-stigmastadienol	0.0076	0.0022	0.0086
Sitostanol	NR	0.0028	<0.0003
Sitostanol + delta-5-avenasterol	0.0072	NR	NR
Sitosterol, beta	0.0520	0.0610	0.0186
Stigmasterol	0.0226	0.3413	<0.0204
Subtotal of identified plant sterols + stanols	0.3122**	0.54*	0.15*
Unidentified sterols	0.1722	Not reported	Not reported
Total plant sterols + stanols	0.48	0.54	0.15

* The values represent total sterols in fats (wt%). Like other DHA-rich oil (GRN 677), it is assumed that Hubei Fuxing's DHA oil is composed of 99-100% fats. It is noteworthy that GRNs 553 and 677 reported fatty acid values as %area without reporting the absolute quantity.

** The subtotal of identified plant sterols + plant stanols was based on average value reported in COAs.

9. Please correct the following reference errors:

a) In Table 7 on page 17 of the notice, a specification for DPA is listed for GRN 000553. However, GRN 000553 does not have a specification for DPA, but rather for EPA.

Hubei Fuxing's Response

Thank you for pointing out the error. We have amended Table 7 as shown below to correct the error.

b) In Table 7 on page 17 of the notice, the specification for unsaponified matter is listed as ≤3.0 for GRN 000731; however, on page 18 of GRN 000731 the specification is shown as ≤1.0.

Hubei Fuxing's Response

Thank you for pointing out the error. We have amended Table 7 as shown below to correct the error.

Please see the revised Table 7. The yellow highlights indicate amendments.

Table 7. Specifications of DHA-Rich Oil

Parameter	Specifications							Methods of Analysis for the Current Notice
	Current notice	GRN 137[a]	GRN 553[b]	GRN 677[b]	GRN 731[b]	FCC[c]	FCC[d]	
DHA*, %	≥36[e]	32 – 45[f]	≥35[f]	≥35[f]	>45[e]	30-40[f] ≥30	35-47[f] ≥35	AOCS Ce 2-66; AOCS Ce 1-62; or AOCS Ce 2-66 mod; AOCS Ce 1b-89 mod.
Acid value, mg potassium hydroxide (KOH)/g	≤ 0.8	≤0.5		≤0.5	< 0.5			AOCS Cd 3d-63
Free fatty acid, as % oleic acid	≤ 0.4		≤0.4		< 0.1	≤ 0.4	≤ 0.4	AOCS Cd 3d-63; or AOCS Ca 5a-40
Trans fatty acids, relative area %	≤1.0	≤2.0	≤3.5	≤2.0	<1.0			AOCA Ce 1f-96
Unsaponifiable matter, %	≤3.0	≤4.5	≤3.5	≤3.5	<1.0	≤4.5	≤3.5	AOCS Ca 6b-53
Peroxide value, meq/kg	≤5.0	≤5.0	≤5.0	≤5.0	<5.0	≤5.0	≤5.0	AOCS Cd 8-53
Moisture (direct drying method), wt%	≤0.1	≤0.1	≤ 0.02	≤ 0.05	<0.1			AOCS Ca 2e-84
Docosapentaenoic acid* (DPA, n-6)		10 - 20						AOCS Ce 2-66; AOCS Ce 1-62; or AOCS Ce 2-66 mod; AOCS Ce 1b-89 mod.
Eicosapentaenoic acid (EPA)			≤10					
Copper, ppm	≤0.1	≤0.1	≤0.1	<0.1	<0.5			BS EN ISO 17294-2 2016 mod. except Iron - Eurofin internal method ICP-OES
Iron, ppm	≤0.1	≤0.5	≤0.2	<0.2	<0.2			
Lead, ppm	≤0.1	≤0.2	≤0.1	< 0.1	< 0.1	≤0.1	≤0.1	
Arsenic, ppm	≤ 0.1	≤0.5	≤ 0.1	< 0.1	< 0.1	≤ 0.1	≤ 0.1	
Cadmium, ppm	≤0.1		≤ 0.1		< 0.1			
Mercury, ppm	≤0.04	<0.2	≤0.04	< 0.1	< 0.01	≤ 0.1	≤ 0.1	BS EN 13806:2002
Coliforms, cfu/mL	≤10				< 1**			AOAC 991.14
Molds, cfu/ml	≤10				< 1			AOAC 997.02
Yeast, cfu/ml	≤10				< 1			
Salmonella/25 g	ND				ND			ISO 6679-1:2017
Cronobacter sp./10 g	ND							ISO 22964:2017

AOAC = Association of Official Analytical Chemists; AOCS = American Oil Chemist's Society; BS-EN = British adoption of a European (EN) standard; CFU = Colony Forming Units; ICP OES = inductively coupled plasma optical emission spectrometer; mod=modifications; MPN = most probable number; NA = not available; meq = milliequivalents; ND = not detected; ISO=International Organization for Standardization.
*The samples analyzed in 2019 used AOCS Ce 2-66; AOCS Ce 1-62; and a sample analyzed in 2020 was based on AOCS Ce 2-66 mod; AOCS Ce 1b-89 mod. **Based on cfu/mL.
[a]DHA-rich oil derived from *Schizochytrium* sp. for selected general food applications;
[b]DHA-rich oil derived from *Schizochytrium* sp. for infant formula applications;
[c]FCC specifications for DHA oil derived from *Schizochytrium* sp.;
[d]FCC specifications for DHA oil derived from *Crypthecodinium cohnii*.
[e] wt% (Eurofins' COAs have reported the DHA content in wt%).
[f]relative area%.

c) On page 26 of the notice (Section 3.A. Exposure Estimates) Hubei Fuxing cites page 25 of GRN 000732 for food categories. While a description of the exposure estimates is included on page 25 of GRN 732, the food categories are not. The food categories are listed on pages 4-5 of GRN 000732.

Hubei Fuxing's Response

We have amended the page numbers. Now it reads as follows: "These are the same food categories (except egg, meat, poultry, and fish products) found in the GRAS notifications for DHA-algal oils (GRN 137, stamped pages 10 to 12 and 27 to 28 - FDA, 2004; GRN 732, pages 4 to 5 - FDA, 2018b) for which the agency did not raise any objections to the companies' conclusion that DHA-algal oils derived from *Schizochytrium* sp. would be considered GRAS when used in the food categories identified for menhaden oil."

Microbiology:

10. In Table 8 on page 19 of the notice, the microbiological specifications and batch analysis data are presented. Please confirm that the Salmonella serovars specification sample size is 25 g and not 25 mL.

Hubei Fuxing's Response

Thank you for pointing out the error. We have verified with Eurofins, which provided the certificates of analysis. In Tables 7 and 8, we have amended the sample size from 25 mL to 25 g. The certificates of analysis are shown at the end of this document. The revised Table 7 is shown on pages 6 to 7 of this response document, and the revised Table 8 now reads as follow:

Table 8. Summary of Analytical Values for Hubei Fuxing's DHA-Rich Oil*

Parameter	Analytical values						
	D18071 101J	D18081 801J	D18111 401J	D18122 601J	D19122 101D	D181272 701J	LOQ
DHA, wt%	38.24	38.06	38.78	38.30	40.95		0.02
Acid value, mg KOH/g	0.52	0.34	0.38	0.38	0.14		0.05
Free fatty acid, as % oleic acid	0.26 / 0.18	0.17 / 0.18	0.19 / 0.20	0.19 / 0.14	0.07 / 0.07		0.01
Trans fatty acids, relative area %	0.20	0.12	0.15	<0.01	0.07		0.01
Unsaponifiable matter, %	1.66	1.04	1.58	1.03	1.87		0.05
Peroxide value, meq/kg	<0.1	2.1	<0.1	1.1	1.9		0.1
Moisture, g/100 g	0.02	0.02	0.02	0.01	0.04%		0.01
Protein, g/100 g	<0.1	<0.1	<0.1	<0.1	<0.1		0.1
Ash, g/100 g	0.04	0.03	0.03	0.05	0.020		0.01
Potassium (K), mg/kg					<3		3
Manganese (Mn), mg/kg	<0.1	<0.1	<0.1	<0.1	<0.1		0.1
Sulphur (S), mg/kg					<20		20
Copper (Cu), mg/kg	<0.1	<0.1	<0.1	<0.1	<0.1		0.1
Iron (Fe), mg/100 g	<0.1	<0.1	<0.1	<0.1	<0.3		<0.3
Lead (Pb), mg/kg	<0.05	<0.05	<0.05	<0.05	<0.05		0.05
Arsenic (As), mg/kg	<0.05	<0.05	<0.05	<0.05	<0.05		0.05
Cadmium (Cd), mg/kg	<0.01	<0.01	<0.01	<0.01	<0.01		0.01
Mercury (Hg), mg/kg	<0.005	<0.005	<0.005	<0.005	<0.005		0.005
Coliforms, cfu/mL	<10	<10	<10	<10	<10		NA
Molds, cfu/g	<10	<10	<10	<10	<10		NA
Yeast, cfu/g	<10	<10	<10	<10	<10		NA
Salmonella/25 g	ND	ND				ND	NA
Cronobacter sp./10 g	ND	ND	ND	ND	ND		NA

*Samples were taken from 3-5 non-consecutive batches. NA=not available; ND = Not detected; LOQ=limit of quantitation.

11. Please confirm that the manufacturer continuously monitors the fermentation process for contaminants and quality control procedures are taken upon observation of contamination.

    Hubei Fuxing's Response
    We have confirmed with Hubei Fuxing that the company continuously monitors the fermentation process for contaminants, and quality control procedures are taken upon observation of contamination. We are adding a sentence ("Hubei Fuxing continuously monitors the fermentation process for contaminants, and quality control procedures are taken upon observation of contamination") to page 12 right after the following sentence: **"**Hubei Fuxing observes the principles of Hazard Analysis Critical Control Point (HACCP)-controlled manufacturing process and current good manufacturing practices (cGMP) and rigorously tests its final production batches to verify adherence to quality control specifications."

Toxicology:

12. On page 34 of the notice, Hubei Fuxing states "The studies reviewed in these GRAS notices include bacterial reverse mutation assays (Hammond et al., 2002; FedorovaDahms et al., 2011a, 2011b; Lewis et al., 2016; Schmitt et al., 2012a), chromosome aberration assays (Fedorova-Dahms et al., 2011a, 2011b; Hammond et al., 2002; Lewis et al. 2016; Schmitt et al., 2012a), in vivo micronucleus tests in mice and rats (Fedorova-Dahms et al., 2011a, 2011b; Hammond et al., 2002; Lewis et al., 2016; Schmitt et al., 2012b), mammalian erythrocyte micronucleus tests (Lewis et al., 2016), and in vitro CHO AS52/XPRT gene mutation assay (Hammond et al., 2002)."

    a) Please note that the reference Schmitt et al. (2012b) listed for the in vivo micronucleus tests is incorrect; no such study was included in that article. Please confirm if Schmitt et al. (2012a) was intended here instead.

    Hubei Fuxing's Response
    We agree that Schmitt et al. (2012a) is the correct reference.

    b) Hubei Fuxing cites Lewis et al. (2016) in the context of the following studies: (1) bacterial reverse mutation assay, (2) chromosome aberration assay, (3) in vivo micronucleus test in rats, and (4) mammalian erythrocyte micronucleus test. Please consult Lewis et al. (2016) and find out whether this publication has indeed discussed all four above-mentioned tests. If not, please modify the above statement accordingly.

    Hubei Fuxing's Response
    Lewis et al. (2016) includes the following three studies: (1) bacterial reverse mutation assay, (2) chromosome aberration assay, and (3) mammalian erythrocyte micronucleus

test, but not *in vivo* micronucleus test in rats. Thus, we have amended the sentence as follows: "The studies reviewed in these GRAS notices include bacterial reverse mutation assays (Hammond et al., 2002; Fedorova-Dahms et al., 2011a, 2011b; Lewis et al., 2016; Schmitt et al., 2012a), chromosome aberration assays (Fedorova-Dahms et al., 2011a, 2011b; Hammond et al., 2002; Lewis et al. 2016; Schmitt et al., 2012a), *in vivo* micronucleus tests in mice and rats (Fedorova-Dahms et al., 2011a, 2011b; Hammond et al., 2002; Schmitt et al., 2012a), mammalian erythrocyte micronucleus tests (Lewis et al., 2016), and *in vitro* CHO AS52/XPRT gene mutation assay (Hammond et al., 2002)."

13. On page 38 of the notice in Table 14 for the Schmitt et al. (2012b) study:

a) The "dose" is provided as "0.5, 1.0, 2.5, or 5% in the diet." On page 4151 of the article by Schmitt et al. (2012b) in section 2.2.2. Experimental design, the test article target concentrations are listed as 0, 10,000, 25,000, and 50,000 ppm for algal oil or 0, 1, 2.5, and 5%, respectively. In addition, another group of animals received 50,000 ppm fish oil corresponding to 5%. Please confirm that 0.5% was not one of the dose levels administered.

Hubei Fuxing's Response

We agree that 0.5% was not one of the dose levels administered. Thus, we have amended the doses of Schmitt et al. (2012b) as 0, 1.0, 2.5, or 5% in the diet.

b) The NOAELs for systemic toxicity of F1 female and male rats are given as 2.5% and 5%, respectively. For ease of comparison of this NOAEL to the proposed intake levels for Hubei Fixing's DHA-rich oil and to be consistent with the units for other NOAELs, please provide the above NOAELs in units of mg/kg body weight (bw)/day.

Hubei Fuxing's Response

The NOAELs for systemic toxicity of F1 female (F) and male (M) rats were 3,526 (M) and 2,069 (F) mg/kg body weight (bw)/day.

c) This study is a combined 90-day/one-generation reproductive toxicity study in which no reproductive toxicity was reported in F0 females, but systemic toxicity was observed in F1 females at the high dose level (5%) when administered DHArich oil for 110-111 days. Consequently, the NOAEL was stated to be 2.5% for females for systemic toxicity. The study authors identify this arm of the study as a "3-month rat dietary toxicity study with an *in utero* exposure phase"; as such, it is a subchronic toxicity study, with a subchronic NOAEL of 2.5%. On page 49 of the notice, Hubei Fuxing states that "The NOAEL was determined to be 3,149 mg/kg bw/day in a subchronic toxicity study in rats." with no reference provided. While it is not clear from Hubei Fuxing's statement, based on the context, we assume this sentence aims to state that 3,149 mg/kg bw/day is the overall lowest NOAEL from all subchronic toxicity studies. Please confirm that our

assumption is correct. If incorrect, please explain the reason for this sentence within that context. As the NOAEL of 2.5% in the Schmitt et al. (2012b) study is a subchronic NOAEL, depending on the value of the equivalent dose of 2.5% in units of mg/kg bw/day, the above statement for the overall lowest NOAEL for all subchronic toxicity studies may need to be updated. Additionally, if our above assumption is correct, please rewrite the sentence to make it clearer that this is the lowest overall NOAEL for all subchronic toxicity studies.

Hubei Fuxing's Response

Based on the NOAEL of 2.5% determined for F1 females in the Schmitt et al. (2012b) study, we have amended the NOAEL to 2,069 mg/kg bw/day. It now reads as follows: "The NOAEL was determined to be 2,069 mg/kg bw/day in a subchronic toxicity study in rats (Schmitt et al., 2012b)."

14. On page 39 of the notice in Table 14, the NOAEL for pigs in the Abril et al., 2003 study is provided as kg/pig. For ease of comparison to proposed intake levels for Hubei Fixing's DHA-rich oil and to be consistent with the units for other NOAELs, please provide the NOAEL in units of mg/kg bw/day.

Hubei Fuxing's Response

Abril et al. (2003) did not report feed consumption and did not report the NOAEL on a mg/kg bw basis. We have revised the dossier to eliminate any estimate of DHA or DHA-rich oil NOAEL for this study. Description about Abril et al. (2003) (page 35) and Table 14 (page 39) have been revised as follows.

Studies of DHA-Rich Microalgae from *Schizochytrium* sp.

For DHA-rich microalgae (DRM), the highest dose tested was 5.746 kg DRM per pig, corresponding to 1.281 kg DHA per pig (DRM contained 22.3% DHA) (Abril et al., 2003). The DHA supplementation at all doses did not result in treatment-related adverse effects on measured outcomes such as clinical observations, body weights, food consumption, mortality, hematologic values, gross necropsy findings, organ weights or histopathology in pigs. However, the authors did not provide the feed consumption or NOAEL on a kg bw/day basis.

DRM Studies Reviewed in Previous GRAS Notices						
Sub-chronic toxicity (diet)	2.680, 1.169, 3.391, or 5.746 kg DRM per pig (22.3% DHA on a	2.680 kg DRM/pig-120 d, a whole-life exposure; 1.169, 3.391, or 5.746 kg DRM/pig during the last 42 d	Pig (M)	No treatment-related adverse effects for low-, mid-, and high-dose groups (261, 756, and 1,281 g DHA per pig during expt. period)	No feed consumption data on a mg/kg bw basis; no NOAEL was reported	Abril et al., 2003

	dry wt basis)					

If we are allowed to roughly estimate the DHA intake, we may be able to use the following calculation method. The abstract and page 79 stated that the total DHA administered during the last 42-day period was 1,281 g of DHA for pigs in the high dose-DRM groups. To calculate the average daily intake of DHA, we divided the total DHA administered to each pig (mg/pig) by 42. For T4, we got 30,500 mg DHA/day.
In the absence of average body weight during the last 42-day period, we assumed that the body weight gain was constant during the 120-day period. Based on the initial and final body weight values listed on Tables 5 to 6 and the daily body weight gain shown in Table 7, we calculated the average body weight at day 79 for the T4 group. For example, body weight of T4 at day 79 was calculated using the following formula: (122.32 kg bw at day 120) – (42 d x 0.943 kg body weight gain/day) = 122.32 - 39.61 = 82.71 kg at day 79. To calculate the average body weight during the last 42 days, we took an average value between 82.71 and 122.32 kg, which is 102.515 kg bw. Then, we divided the average daily intake value of 30,500 mg DHA/day by 102.515 kg bw to derive 297.5 mg DHA/kg bw/day for the T4 group, the high-dose group. However, since the authors did not provide feed consumption or NOAEL on a mg/kg bw basis, we will not use such a roughly estimated value.

15. For the Abril et al. (2003) and the Hammond et al. (2001a,b,c) studies please show how Hubei Fuxing calculated NOAELs expressed as DHA-rich oil/mg kg bw/day and DHA/kg bw/day from DRM/kg bw/day.

Hubei Fuxing's Response

Abril et al. (2003) did not report feed consumption and the NOAEL on a mg/kg bw basis. We have revised the dossier to eliminate any estimate of DHA or DHA-rich oil NOAEL for this study.

In the study by Hammond et al. (2001a), the authors reported that the NOAEL as 4,000 mg DRM/kg bw/day in rats and that DRM contained 8.7% DHA on a dry weight basis (page 193). The corresponding DHA level was calculated based on the following formula: *x* mg DRM x 0.087 (% DHA on a dry wt. basis) = *y* mg DHA. Thus, the corresponding DHA level is 348 mg/kg bw/day (4,000 x 0.087 = 348 mg DHA) on a dry weight basis.

We assumed that a typical DHA-rich oil tested in many toxicity studies contained approximately 40% DHA. We calculated DHA-oil values by dividing the DHA level by 0.4. However, the authors did not provide such a value, and thus, we withdraw all statements on corresponding DHA-rich oil value.

Revised descriptions about Hammond 2001a, 2001b, 2001c (pages 35 and 36) and Table 14 (pages 39-40) are shown below (after deleting all statements related to corresponding DHA-rich oil value).

2) In a subchronic toxicity study on another source of DRM, ----. Thus, corresponding DHA level is 348 mg/kg bw/day (4,000 x 0.087 = 348 mg DHA/kg bw/day on a dry weight basis).

However, in a reproductive and developmental toxicity study in rabbits by Hammond et al. (2001b), ---. ---- In summary, the NOAELs were determined to be 600 mg/kg bw/day for maternal toxicity and 1,800 mg/kg bw/day, the highest level tested, for developmental toxicity in rabbits. These levels correspond to 52 mg DHA/kg bw/day for maternal toxicity and 157 mg DHA/kg bw/day for developmental toxicity in rabbits assuming the DHA content in DRM was 8.7% on a dry weight basis (600 mg DRM/kg bw/day x 0.087= 52 mg DHA/kg bw/day; 1,800 mg DRM/kg bw/day x 0.087 = 157 mg DHA/kg bw/day). However, the authors noted that abortions occur spontaneously -- within historical limits for the laboratory.

It is noteworthy that -- (Hammond et al., 2001b). In rats, the NOAEL was estimated to be 22,000 mg DRM/kg bw/day for both maternal and development toxicity. This level corresponds to 1,914 mg DHA /kg bw/day, assuming the DHA content in DRM was 8.7% on a dry weight basis.

In a single generation reproductive toxicity study, the NOAEL was estimated to be 17,847 and 20,669 mg DRM/kg bw/day for males and females, respectively (Hammond et al., 2001c). The authors stated that the levels of DRM intake for males and females correspond to intakes of approximately 1,512 and 1,680 mg DHA/kg bw/day, respectively (page 358 of Hammond et al., 2001c).

Subchronic toxicity (diet)	400, 1,500, or 4,000 mg/kg bw/d (8.7% DHA on a dry wy basis)	13 wk	Rat	No treatment-related adverse effects	4,000 DRM (corresponding to 348 DHA*)	Hammond et al., 2001a
Reproduc-tive and develop-mental toxicity (diet)	0.6, 6.0, or 30% DRM in diet (8.7% DHA on a dry wt. basis)	Gestation days 6 to15	Rat	No treatment-related adverse effects	Both maternal and developmental toxicity - 22,000 DRM (corresponding to 1,914 DHA*)	Hammond et al., 2001b

Single-generation reproduction toxicity (diet)		M-15 wk; F-2 weeks prior to mating, during mating, and throughout gestation and lactation (10 wk)	Rat	No treatment-related adverse effects	17,847 DRM (corresponding to 1,512 DHA**) (M); 20,669 DRM (corresponding to 1,680 DHA**) (F)	Hammond et al., 2001c
Reproduc-tive and develop-mental toxicity (gavage)	180, 600, or 1,800 mg DRM/kg/d (8.7% DHA on a dry wt basis)	F_0 mother-13 d (gestation days 6 to 18)	Rabbit	High-dose (1,800) DHA oil and fish oil groups: F_0 mothers had reduced food consumption and body weight and a slightly higher abortion rate (but within the historical limits for the laboratory)	F_0: 600 DRM (corresponding to 52 DHA*) (F); F_1: Developmental, 1,800 DRM (corresponding to 157 DHA*) (both M and F)	Hammond et al., 2001b

*DHA values are on a dry weight basis.
**From Hammond et al. (2001c), page 358.

16. On page 49 of the notice, Hubei Fuxing states that "This estimated DHA intake is consistent with current DHA recommendations for preterm and term infants of 18 to 60 mg/kg bw/day depending on gestational age." Please provide a reference for the "current DHA recommendations for preterm and term infants of 18 to 60 mg/kg bw/day."

Hubei Fuxing's Response
The references are Koletzko et al. (2014a,b).
Now it reads as follows: "This estimated DHA intake is consistent with current DHA recommendations for preterm and term infants of 18 to 60 mg/kg bw/day depending on gestational age (Koletzko et al., 2014a,b)."

Koletzko B, Boey CC, Campoy C, Carlson SE, Chang N, Guillermo-Tuazon MA, Joshi S, Prell C, Quak SH, Sjarif DR, Su Y, Supapannachart S, Yamashiro Y, Osendarp SJ. Current information and Asian perspectives on long-chain polyunsaturated fatty acids in pregnancy, lactation, and infancy: systematic review and practice recommendations from an early nutrition academy workshop. Ann Nutr Metab. 2014a;65:49-80.

Koletzko B, Poindexter B, Uauy R: Recommended nutrient intake levels for stable, fully enterally fed very low birthweight infants;in Koletzko B, Poindexter B, Uauy R (eds):

Nutritional Care of Preterm Infants. Basel, Karger, 2014b, pp 300–305.

17. The designation of "exempt" infant formula includes a number of different formulations for subpopulations with specific needs or afflictions. We note that the physiology of the gastrointestinal system between premature infants and term infants with food allergies may be quite different. Please provide a short narrative describing Hubei Fixing's rationale and safety conclusion that algal oil (≥36% DHA) is not expected to adversely impact the specific infant subpopulations who would be consuming these exempt infant formulae.

Hubei Fuxing's Response

Two preterm infant studies specifically discussed the effects of DHA supplementation on gastrointestinal (GI) adverse events or food allergy. These studies did not report adverse effects/events associated with DHA supplementation in preterm infants (Clandinin et al., 2005; Manley et al., 2011).

In a study by Clandinin et al. (2005), 361 preterm infants < 35 postmenstrual age (PMA) were randomly assigned to 3 study formula groups: 1) control, formulas with no added DHA or ARA; (2) algal-DHA, formulas with 17 mg DHA/100 kcal from algal oil and 34 mg ARA/100 kcal from fungal oil (Martek Biosciences, algal type was not specified); or (3) fish-DHA, formulas with 17 mg DHA/100 kcal from tuna fish and 34 mg ARA/100 kcal from fungal oil. These levels of DHA and ARA are similar to those present in a typical mature human milk (approximately 0.3 wt% of fatty acids as DHA and 0.6 wt% as ARA). The study formulas were the sole source of nutrition for preterm subjects until 57 weeks PMA (or 4 months after term) and the primary source of nutrition until 92 weeks PMA. DHA supplementation was stopped at 92 weeks PMA, and the subjects were monitored until 118 weeks PMA (18 months after term). Term infants breast-fed for 4 months or longer were a reference group. All infants were assessed at birth and at 40, 44, 48, 53, 57, 66, 79, 92, and 118 weeks PMA. Measurement endpoints included growth, tolerance, adverse events, and Bayley development scores. There were no differences in caloric intake from formula, daily gastric residuals, stool frequency, stool consistency, or abdominal distention among the preterm groups during hospitalization (data not shown). In addition, there were no differences in parents reporting fussiness, diarrhea, or constipation (data not shown), although infants in the algal DHA and fish DHA-supplemented groups had more gas than usual at 40 and 44 weeks post-menstrual age ($p<0.05$), which reached no differences at 53 or 57 weeks. Overall, the authors concluded that DHA supplementation (either algal oil or fish oil source) did not increase morbidity or adverse events in preterm infants. In addition, no adverse effects of DHA supplementation were reported on the measured outcomes.

In a study of Manley et al. (2011), 657 preterm infants of <33 weeks of gestation were enrolled. They consumed expressed breast milk from mothers taking either tuna oil with high-DHA (tuna oil) or standard-DHA (soy oil) capsules. Lactating women with their

infants were randomly assigned to the high-DHA group (3 g tuna oil per day) or the standard-DHA group (3 g soy oil per day to achieve a breast milk DHA concentration that was 1% or 0.35% of total fatty acids without altering the naturally occurring concentration of arachidonic acid [AA] in breast milk). If supplementary formula was required, infants were given a high-DHA preterm formula (1% DHA and 0.6% AA) or a standard preterm infant formula (0.35% DHA and 0.6% AA). The intervention in both groups continued until infants reached their expected date of delivery. Measurement endpoints included neurodevelopment, important allergic parameters (risk of asthma, eczema, or requirement for special diet for food allergy), and respiratory parameters (incidence of bronchopulmonary dysplasia) over the first 18 months of life. No adverse effects of DHA supplementation were noted on the measured outcomes including requirement for special diet for food allergy in pre-term infants of <33 weeks of gestation.

Other studies also reported no adverse events or effects of DHA supplementation in preterm infants (Fang et al., 2015, DHA source, not specified; Gunaratne et al., 2019, DHA source-fish oil). Measurement endpoints included cognitive development, visual acuity, vital signs and adverse events (Fang et al., 2015) and allergic respiratory symptoms (wheeze or rhinitis) at 7 years of corrected age and the incidence and severity of parent-reported allergic disease symptoms (Gunaratne et al., 2019).

In addition, GRNs 000379, 000553, and 000677 presented comprehensive summaries of clinical study literature regarding supplementation of DHA or long-chain polyunsaturated fatty acids from fish and algal oil sources to infant formula (FDA, 2011a, 2015, 2017). These GRAS notices concluded that supplementation of DHA (from fish and algal sources), in combination with ARA, to infant formula was safe in both preterm and term infants.

Findings from intervention studies are further supported by the safe history of use of DHA from algal oil in infant formula. The FDA analyzed the CFSAN Adverse Event Reporting system (CAERS) data to find any a correlation between the gastrointestinal (GI) adverse events and the use of DHA and ARA oils in infant formulas (FDA, 2011b; FDA Docket No. 2008-P-0074-0017). FDA considered the USDA reports, which indicated the time-dependent increase of market shares of infant formulas containing DHA and ARA-oils: the market share of infant formulas containing DHA and ARA oils were introduced into the U.S. market in 2002, and increased from less than 10% of the market in the third quarter of 2002 to 98% of the market in 2008. The agency did not find any time-dependent increase in the proportions of GI adverse events to total adverse events reported over time while the market share of infant formula containing DHA and ARA oils increased from 0% to 98%. FDA (2011) stated that "We found no statistically significant increases in the proportion of GI adverse events reports in CAERS when we looked over the time interval from when infant formulas containing DHA and ARA oils

were first introduced until they essentially replaced non-supplemented formula in the market place"

Taken together, algal oil (≥36% DHA) is not expected to adversely impact the pre-term infants who would be consuming exempt infant formula.

References

Clandinin MT, Van Aerde JE, Merkel KL, et al. Growth and development of preterm infants fed infant formulas containing docosahexaenoic acid and arachidonic acid. J Pediatr. 2005;146(4):461-8.

Fang PC, Kuo HK, Huang CB, et al. The effect of supplementation of docosahexaenoic acid and arachidonic acid on visual acuity and neurodevelopment in larger preterm infants. Chang Gung Med J. 2005;28(10):708-15.

FDA. 2011a. GRN 000379. Tuna oil, filed by Ocean Nutrition Canada Ltd. Date of closure, Nov. 8, 2011. Available at http://wayback.archive-it.org/7993/20171031045353/https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM276115.pdf.

FDA. 2011b. Agency response Letter to a petition, filed by Cornucopia Institute, Docket No. FDA-2008-P-0074. Available at https://www.regulations.gov/document?D=FDA-2008-P-0074-0017.

FDA. 2015. GRN 000553. Algal oil (40% docosahexaenoic acid) derived from *Schizochytrium* sp., filed by DSM Nutritional Products. Date of closure, June 19, 2015. Available at http://wayback.archive-it.org/7993/20171031040128/https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM456952.pdf.

FDA. 2017. GRAS Notice No. GRN000677. Docosahexaenoic acid oil produced in *Schizochytrium* sp., filed by Mara Renewables Corporation. Date of closure, May 2, 2017. Available at https://www.fda.gov/media/101431/download.

Gunaratne AW, Makrides M, Collins CT, Gibson RA, McPhee AJ, Sullivan TR, Gould JF, Green TJ, Doyle LW, Davis PG, French NP, Colditz PB, Simmer K, Morris SA, Best KP. Docosahexaenoic acid supplementation of preterm infants and parent-reported symptoms of allergic disease at 7 years corrected age: follow-up of a randomized controlled trial. Am J Clin Nutr. 2019;109(6):1600-10.

Manley BJ, Makrides M, Collins CT, McPhee AJ, Gibson RA, Ryan P, Sullivan TR, Davis PG; DINO Steering Committee. High-dose docosahexaenoic acid supplementation of preterm infants: respiratory and allergy outcomes. Pediatrics. 2011;128(1):e71-7.

If you have any further questions, please contact me. Thank you very much.

Sincerely,

Susan Cho
NutraSource, Inc. (new company name, AceOne RS)
Susanscho1@yahoo.com or scho@aceoners.com
(301) 875-6454

eurofins

CNAS 中国认可 检测 TESTING CNAS L3788

Analytical Report

Sample Code	502-2020-00083562	Report date	01-Oct-2020
Certificate No.	AR-20-SU-068013-01-EN		

HuBei Fuxing Biotechnology CO,.LTD
NO.18 Fuxing Street, Chenhu Town,
Hanchuan, Hubei Province, P.R. China
Fax 0086 712 8741718

Our reference:	502-2020-00083562/ AR-20-SU-068013-01-EN
Client Sample Code:	D18122701J
Sample described as:	二十二碳六烯酸DHA油脂
Sample Packaging:	Sealed metal bottle
Sample reception date:	28-Sep-2020
Analysis Starting Date:	28-Sep-2020
Analysis Ending Date:	01-Oct-2020
Arrival Temperature (°C)	23.8
Sample Weight	160g

	Results	Unit	LOQ	LOD
^# SU105 Salmonella Method: ISO 6579-1:2017				
Salmonella	Not Detected	/25 g		
^# SU111 E.coli Method: ISO 16649-2:2001				
E.Coli	<10	cfu/g		

SIGNATURE

Melissa He
Authorized Signatory

EXPLANATORY NOTE

LOQ: Limit of Quantification
< LOQ: Below Limit of Quantification
N/A means Not applicable
Sum compounds results are calculated from the results of each quantified compound as set by regulation

^ CNAS # DAkkS =CMA
☆ means the test is subcontracted within Eurofins group
° means the test is subcontracted outside Eurofins group

The sample description and information are provided by the Client. Eurofins is not responsible for verifying the accuracy, relevancy, adequacy and/or completeness of the information provided by the Client.
The analytical result herein is applicable for the sample(s) tested only.
This analytical report shall not be excerpted or modified without prior written approval from Eurofins. The report shall be utilized in full.
The result(s) is(are) only for internal use by the client and not for publicity available as evidence.Without the written permission of Eurofins, any party is prohibited from using the test results and the report for publicity or promotions or marketing.
The Eurofins General Terms and Conditions apply to this analytical report.
For and on behalf of Eurofins Technology Service (Suzhou) Co., Ltd

END OF REPORT

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 216000
Jiangsu Province, P.R.China

Phone +86 400 828 5088
Fax
www.eurofins.cn

Scan QR code to view report

DAkkS Deutsche Akkreditierungsstelle D-PL-14292-01-00

eurofins

CNAS 中国认可 检测 TESTING CNAS L3788

Analytical Report

Sample Code	502-2020-00083561	Report date	01-Oct-2020
Certificate No.	AR-20-SU-068012-01-EN		

HuBei Fuxing Biotechnology CO,.LTD
NO.18 Fuxing Street, Chenhu Town,
Hanchuan, Hubei Province, P.R. China
Fax 0086 712 8741718

Our reference:	502-2020-00083561/ AR-20-SU-068012-01-EN
Client Sample Code:	D18081801J
Sample described as:	二十二碳六烯酸DHA油脂
Sample Packaging:	Sealed metal bottle
Sample reception date:	28-Sep-2020
Analysis Starting Date:	28-Sep-2020
Analysis Ending Date:	01-Oct-2020
Arrival Temperature (°C)	23.8
Sample Weight	130g

	Results	Unit	LOQ	LOD
+# SU105 Salmonella Method: ISO 6579-1:2017				
Salmonella	Not Detected	/25 g		
+# SU111 E.coli Method: ISO 16649-2:2001				
E.Coli	<10	cfu/g		

SIGNATURE

Melissa He
Authorized Signatory

EXPLANATORY NOTE

LOQ: Limit of Quantification
< LOQ: Below Limit of Quantification
N/A means Not applicable
+ CNAS # DAkkS ¤CMA
☆ means the test is subcontracted within Eurofins group
° means the test is subcontracted outside Eurofins group
Sum compounds results are calculated from the results of each quantified compound as set by regulation

The sample description and information are provided by the Client. Eurofins is not responsible for verifying the accuracy, relevancy, adequacy and/or completeness of the information provided by the Client.
The analytical result herein is applicable for the sample(s) tested only.
This analytical report shall not be excerpted or modified without prior written approval from Eurofins. The report shall be utilized in full.
The result(s) is(are) only for internal use by the client and not for publicity available as evidence.Without the written permission of Eurofins, any party is prohibited from using the test results and the report for publicity or promotions or marketing.
The Eurofins General Terms and Conditions apply to this analytical report.
For and on behalf of Eurofins Technology Service (Suzhou) Co., Ltd

END OF REPORT

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R.China

Phone +86 400 828 5088
Fax
www.eurofins.cn

Scan QR code to view report

DAkkS Deutsche Akkreditierungsstelle D-PL-14292-01-00

eurofins

CNAS 中国认可 检测 TESTING CNAS L3788

Analytical Report

Sample Code	502-2020-00083563	Report date	01-Oct-2020
Certificate No.	AR-20-SU-068014-01-EN		

HuBei Fuxing Biotechnology CO,.LTD
NO.18 Fuxing Street, Chenhu Town,
Hanchuan, Hubei Province, P.R. China
Fax 0086 712 8741718

Our reference:	502-2020-00083563/ AR-20-SU-068014-01-EN
Client Sample Code:	D18071101J
Sample described as:	二十二碳六烯酸DHA油脂
Sample Packaging:	Sealed metal bottle
Sample reception date:	28-Sep-2020
Analysis Starting Date:	28-Sep-2020
Analysis Ending Date:	01-Oct-2020
Arrival Temperature (°C)	23.8
Sample Weight	120g

	Results	Unit	LOQ	LOD
^# SU105 Salmonella Method: ISO 6579-1:2017				
Salmonella	Not Detected	/25 g		
^# SU111 E.coli Method: ISO 16649-2:2001				
E.Coli	<10	cfu/g		

SIGNATURE

Melissa He
Authorized Signatory

EXPLANATORY NOTE

LOQ: Limit of Quantification
< LOQ: Below Limit of Quantification
N/A means Not applicable
Sum compounds results are calculated from the results of each quantified compound as set by regulation

^ CNAS # DAkkS ¤CMA
☆ means the test is subcontracted within Eurofins group
° means the test is subcontracted outside Eurofins group

The sample description and information are provided by the Client. Eurofins is not responsible for verifying the accuracy, relevancy, adequacy and/or completeness of the information provided by the Client.
The analytical result herein is applicable for the sample(s) tested only.
This analytical report shall not be excerpted or modified without prior written approval from Eurofins. The report shall be utilized in full.
The result(s) is(are) only for internal use by the client and not for publicly available as evidence.Without the written permission of Eurofins, any party is prohibited from using the test results and the report for publicity or promotions or marketing.
The Eurofins General Terms and Conditions apply to this analytical report.
For and on behalf of Eurofins Technology Service (Suzhou) Co., Ltd

END OF REPORT

Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 216000
Jiangsu Province, P.R.China

Phone +86 400 828 5088
Fax
www.eurofins.cn

Scan QR code to view report

DAkkS Deutsche Akkreditierungsstelle D-PL-14292-01-00

From:	Susan S Cho
To:	Morissette, Rachel
Subject:	Re: follow-up question for GRN 000933
Date:	Friday, October 9, 2020 5:27:13 PM
Attachments:	GRN 933 Revised Response to FDA Question No. 17 10-9-2020r.pdf image001.png

---

Dear Dr. Morissette,

I am sending you a re-revised version of our response to FDA Question No. 17. Please see the attached. Please ignore the version I sent you about 35 minutes ago. The only change we made was the very last paragraph, Conculusion.

The last paragraph now reads as follows: In conclusion, algal oil (≥36% DHA), in combination with a safe and suitable source of ARA, is not expected to adversely impact the preterm and term infants who would be consuming exempt and non-exempt infant formulae, respectively.
I apologize for the inconvenience. Have a nice weekend!

Sincerely,
Susan
Susan Cho, Ph.D. NutraSource, Inc.
+1-410-531-3336 (O) +1-301-875-6454 (C)

On Friday, October 9, 2020, 04:49:20 PM EDT, Susan S Cho <susanscho1@yahoo.com> wrote:

Dear Dr. Morissette,

We have revised our response to FDA Question No. 17 in the attached document. We would be happy to provide you with any furtehr information you may need. Thank you very much. Have a nice weekend!

Sincerely,
Susan
Susan Cho, Ph.D.
NutraSource, Inc.
+1-410-531-3336 (O) +1-301-875-6454 (C)

On Thursday, October 8, 2020, 01:42:18 PM EDT, Morissette, Rachel <rachel.morissette@fda.hhs.gov> wrote:

Dear Dr. Cho,

Thank you for sending your responses. However, your response to question 17 does not fully address our question. While you provided a safety narrative for pre-term infants, you did not provide a safety narrative for term infants whose physiological conditions necessitate their consumption of hypoallergenic/hydrolyzed formulas (i.e., amino acid-based and extensively hydrolyzed-based). Please provide an additional narrative that discusses why the gastrointestinal physiology of these infants still allows for the safe consumption of your ingredient and/or how the data and information from studies involving pre-term infants relates to your GRAS conclusion for term infants consuming these specialized

formulas.

Thank you for your attention to this matter.

Best regards,

Rachel

Rachel Morissette, Ph.D.
Regulatory Review Scientist

Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
rachel.morissette@fda.hhs.gov

From: Susan S Cho <susanscho1@yahoo.com>
Sent: Tuesday, October 6, 2020 2:56 PM
To: Morissette, Rachel <Rachel.Morissette@fda.hhs.gov>
Subject: Re: questions for GRN 000933

Dear Dr. Morissette,

Please see Hubei Fuxing's response to FDA questions in the attached document. We hope we answered FDA questions properly. If you need further clarifications, please contact me. Thank you. Please stay healthy during this pandemic!

Sincerely,

Susan

Susan Cho, Ph.D.

NutraSource, Inc.

+1-410-531-3336 (O) +1-301-875-6454 (C)

On Wednesday, September 23, 2020, 12:46:39 PM EDT, Morissette, Rachel <rachel.morissette@fda.hhs.gov> wrote:

Dear Dr. Cho,

Please see attached our questions for GRN 000933.

Best regards,

Rachel

Rachel Morissette, Ph.D.
Regulatory Review Scientist

Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
rachel.morissette@fda.hhs.gov

October 9, 2020

To: Dr. Rachel Morissette

Subject: Revised response to FDA Question 17 related to GRN 933, algal oil (≥36% docosahexaenoic acid) from *Schizochytrium* sp. strain "DHF" (algal oil (≥36% DHA))

From: Susan Cho, NutraSource, Inc. (new company name, AceOne RS)

Dear Dr. Morissette,

On behalf of Hubei Fuxing, we have revised our response to FDA question 17 as follows.

17. The designation of "exempt" infant formula includes a number of different formulations for subpopulations with specific needs or afflictions. We note that the physiology of the gastrointestinal system between premature infants and term infants with food allergies may be quite different. Please provide a short narrative describing Hubei Fixing's rationale and safety conclusion that algal oil (≥36% DHA) is not expected to adversely impact the specific infant subpopulations who would be consuming these exempt infant formulae.

    Hubei Fuxing's Response

    Pre-term Infants

    Two preterm infant studies specifically discussed the effects of docosahexaenoic acid (DHA) supplementation on gastrointestinal (GI) adverse events or food allergy. These studies did not report adverse effects or events associated with DHA supplementation in preterm infants (Clandinin et al., 2005; Manley et al., 2011).

    In a study by Clandinin et al. (2005), 361 preterm infants of < 35 postmenstrual age (PMA) were randomly assigned to 3 study formula groups: 1) control, formulae with no added DHA or arachidonic acid (ARA); (2) algal-DHA, formulae with 17 mg DHA/100 kcal from algal oil and 34 mg ARA/100 kcal from fungal oil (Martek Biosciences, algal type was not specified); or (3) fish-DHA, formulae with 17 mg DHA/100 kcal from tuna fish and 34 mg ARA/100 kcal from fungal oil. These levels of DHA and ARA are similar to those present in a typical mature human milk (approximately 0.3 wt% of fatty acids as DHA and 0.6 wt% as ARA). The study formulae were the sole source of nutrition for preterm subjects until 57 weeks PMA (or 4 months after term) and the primary source of nutrition until 92 weeks PMA. DHA supplementation was stopped at 92 weeks PMA, and the subjects were monitored until 118 weeks PMA (18 months after term). Term infants breast-fed for 4 months or longer were the reference group. All infants were assessed at birth and at 40, 44, 48, 53, 57, 66, 79, 92, and 118 weeks PMA.

Measurement endpoints included growth, tolerance, adverse events, and Bayley development scores. There were no differences in caloric intake from formula, daily gastric residuals, stool frequency, stool consistency, or abdominal distention among the preterm groups during hospitalization (data not shown). In addition, there were no differences in parents reporting fussiness, diarrhea, or constipation (data not shown), although infants in the algal DHA and fish DHA-supplemented groups had more gas than usual at 40 and 44 weeks post-menstrual age ($p<0.05$), which reached no differences at 53 or 57 weeks. Overall, the authors concluded that DHA supplementation (either algal oil or fish oil source) did not increase morbidity or adverse events in preterm infants. In addition, no adverse effects of DHA supplementation were reported on the measured outcomes.

In a study of Manley et al. (2011), 657 preterm infants of <33 weeks of gestation were enrolled. They consumed expressed breast milk from mothers taking either tuna oil with high-DHA (tuna oil) or standard-DHA (soy oil) capsules. Lactating women with their infants were randomly assigned to the high-DHA group (3 g tuna oil per day) or the standard-DHA group (3 g soy oil per day to achieve a breast milk DHA concentration that was 1% or 0.35% of total fatty acids without altering the naturally occurring concentration of ARA in breast milk). If supplementary formula was required, infants were given a high-DHA preterm formula (1% DHA and 0.6% ARA) or a standard preterm infant formula (0.35% DHA and 0.6% ARA). The intervention in both groups continued until infants reached their expected date of delivery. Measurement endpoints included neurodevelopment, important allergic parameters (risk of asthma, eczema, or requirement for special diet for food allergy), and respiratory parameters (incidence of bronchopulmonary dysplasia) over the first 18 months of life. No adverse effects of DHA supplementation were noted on the measured outcomes including requirement for special diet for food allergy in preterm infants of <33 weeks of gestation.

Other studies also reported no adverse events or effects of DHA supplementation in preterm infants (Fang et al., 2015, DHA source, not specified; Gunaratne et al., 2019, DHA source-fish oil). Measurement endpoints included cognitive development, visual acuity, vital signs and adverse events (Fang et al., 2015) and allergic respiratory symptoms (wheeze or rhinitis) at 7 years of corrected age and the incidence and severity of parent-reported allergic disease symptoms (Gunaratne et al., 2019). In summary, algal oil (≥36% DHA) is not expected to adversely impact the specific infant subpopulations who would be consuming these exempt infant formulae.

Term Infants

Studies of term infants have not reported adverse events or adverse effects on allergies associated with DHA-supplemented infant formulae.

The study by Burks et al. (2008) evaluated the DHA and ARA supplementation to an amino acid-based formula on overall growth, tolerance, and safety in 164 healthy term

infants. Study 1 compared the effect on growth, tolerance, and safety in healthy infants of an amino acid-based formula (Nutramigen, Mead Johnson) to a control extensively hydrolyzed formula (casein based). Both formulae were supplemented with added DHA (0.32% of total fatty acids; 17 mg/100 kcal, source was not specified) and ARA (0.64% of total fatty acids; 34 mg/100 kcal). These levels are similar to those in human milk worldwide. The formulae were fed from 14 ± 2 through 120 ± 4 days of age. Overall growth, formula acceptance, tolerance, and adverse events were similar between the two groups. No differences between groups were detected in the number of subjects who experienced at least 1 adverse event or the incidence of serious adverse events. The exceptions were parent-reported fussiness that was lower in the control group ($P<0.039$) at age 90 days and the incidence of diarrhea that was significantly higher in the control group (control vs. test groups, 9 vs. 0 infants, $P<0.001$). The authors concluded that the amino acid-based formula with DHA and ARA at levels similar to those in human milk worldwide was hypoallergenic and safe in healthy term infants. The results of the same study were briefly reported in Vanderhoof (2008). In study 2, the hypoallergenicity of the amino acid-based formula containing DHA and ARA was evaluated in 32 infants and children with hypersensitivity to cow's milk. All of the 29 children that completed both the double-blind, placebo-controlled food challenge, with formulae fed in randomized order after a pre-challenge elimination period, and the subsequent open challenge reported no serious adverse events demonstrating the hypoallergenicity of the formula containing DHA.

In a study by Hoffman et al. (2008), 244 healthy term infants received either a soy formula fortified with algal DHA-oil (17 mg DHA/100 kcal) and ARA (34 mg/100 kcal) (test group) or a control formula with no supplementation (control group). Infants received study formulae from 14 to 120 days of age. Body weight and length, head circumference, atopic dermatitis, tolerance, and adverse events were monitored. The incidence of adverse events, formula intake, stool frequency, and stool characteristics were not different between the two groups although gastrointestinal reflux was higher in the control than in the test group (control vs. test: 12 vs. 3 infants, $P = 0.009$). Both formulae were well tolerated as reported by parental assessment of fussiness, diarrhea, and constipation, although a higher incidence of excessive gas was reported in the control group than the test group at 60 days of age (15% vs. 5%, $P = 0.026$). The authors concluded that both formulae were well tolerated and supported normal growth.

In a study by Birch et al. (2010), 343 healthy term infants were randomized to one of four infant formulae: control (0% DHA), 0.32% DHA, 0.64% DHA, or 0.96% DHA (source - algal DHA oil derived from *Crypthecodinium cohnii*); DHA-supplemented formulae also provided 0.64% ARA. Assigned formulae were fed from the time of enrollment (1 to 9 days of life) through age 52 weeks. Visual acuity, red blood cell fatty acids, anthropometric measurements, formula consumption, tolerance, and adverse events were measured or monitored. No differences were observed in the proportions of infants with at least one adverse event or in the numbers with at least one serious adverse event. In any of the 86 symptoms assessed, with the exception of watery eyes

(increased only in the 0.64% DHA group; 0.64% DHA group vs. other 3 groups: 5% vs. 0 to 1%; $P<0.05$). The association between one case of sepsis in an infant in the 0.64% DHA group and diet could not be determined. The authors stated that infants tolerated all formulae well and had normal growth throughout the first 12 months of life.

In the study by Fleddermann et al. (2014), 213 healthy term infants were randomized to receive one of two isoenergetic formulae (a test formula containing DHA, 10.7 mg/100 kcal [source, egg and fish oil], ARA [10.7 mg/100 kcal], and alpha-lactalbumin, or a control formula with standard whey and no long-chain polyunsaturated fatty acids) from less than the first 28 days to 120 days of life. Breast-fed infants served as a reference group. Both formulae were well-accepted, and no differences were reported for acceptance as well as consistency and color of stool, colic, flatulence, and regurgitation and vomiting. The number of serious adverse events was higher in the test group than in the control group (10.2 vs. 3.3%), with one serious adverse event in each formula group considered a potentially association to the study formula (test formula: vomiting, blood in stool, and reflux; control formula: vomiting and blood in stool). However, the total number of adverse events (adverse event plus serious adverse event) was much lower in the test formula and reference groups than the control formula group (test vs. reference vs. control: 24% vs. 24% vs. 45%). The types of adverse events were similarly distributed across the test and control groups. The authors concluded that all infants accepted the test formula supplemented with DHA and ARA well and that no adverse effects were found for all parameters tested.

In the Infant Fish Oil Supplementation study, 420 infants at high risk for atopy were randomized to daily fish oil capsules (providing 0.280 g DHA + 0.110 g eicosapentaenoic acid [EPA]) or placebo capsules (olive oil) from birth to 6 months (D'Vaz et al., 2012). Measurements included polyunsaturated fatty acid levels in 6-month-old infants' erythrocytes and plasma and their mothers' breast milk as well as eczema, food allergy, asthma, and sensitization in 323 infants for whom clinical follow-up was completed at 12 months of age. There was no significant overall difference in the prevalence of food allergy, any allergic disease, overall sensitization, or specific sensitization at 12 months.

Taken together, infant supplementation with DHA did not result in any serious or nonserious adverse events, food allergies, or other allergies in term infants consuming exempt or non-exempt infant formulae, including amino acid-based and extensively hydrolyzed protein-based formulae.

In addition, GRNs 000379, 000553, and 000677 presented comprehensive summaries of clinical study literature regarding supplementation of DHA or long-chain polyunsaturated fatty acids from fish and algal oil sources to infant formula (FDA, 2011a, 2015, 2017). These GRAS notices concluded that supplementation of DHA (from fish and algal sources), in combination with ARA, to infant formula was safe in both preterm and term infants. GRN 933 also summarized the recently published DHA Intake and

Measurement of Neural Development (DIAMOND) study outcomes (Colombo et al., 2017; Lepping et al., 2019). These studies did not report adverse effects of formulae containing algal DHA (up to 0.96% total fatty acids as DHA or up to 51 - 61 mg DHA/kg bw/day) on measurement endpoints such as cognitive functions and concentrations of red blood cell fatty acids in term infants. Overall, algal DHA, up to 0.96% of total fatty acids (or up to 51-61 mg DHA/kg bw/day), in combination with ARA (0.64% of fatty acids) was well tolerated with no side effects in term infants. GRN 933 also briefly discussed the preterm infant studies by Almaas et al. (2015, 2016), which did not report adverse effects of DHA (32 mg/100 mL or 0.86% total fatty acids as DHA) on behavioral and cognitive outcomes at 8 years of age. In these studies, no adverse effects were reported on the measured outcomes and adverse events associated with DHA supplementation were not discussed. Overall, it is concluded that algal DHA supplementation to infant formulae is safe in both term and preterm infants.

Safe History of Use

Findings from intervention studies are further supported by the safe history of use of DHA from algal oil in infant formula. The FDA analyzed the CFSAN Adverse Event Reporting system (CAERS) data to find any a correlation between the gastrointestinal (GI) adverse events and the use of DHA and ARA oils in infant formulae (FDA, 2011b; FDA Docket No. 2008-P-0074-0017). FDA considered the USDA reports, which indicated the time-dependent increase of market shares of infant formulae containing DHA and ARA-oils: the market share of infant formulae containing DHA and ARA oils were introduced into the U.S. market in 2002, and increased from less than 10% of the market in the third quarter of 2002 to 98% of the market in 2008. The agency did not find any time-dependent increase in the proportions of GI adverse events to total adverse events reported over time while the market share of infant formula containing DHA and ARA oils increased from 0% to 98%. FDA (2011b) stated that “We found no statistically significant increases in the proportion of GI adverse events reports in CAERS when we looked over the time interval from when infant formulae containing DHA and ARA oils were first introduced until they essentially replaced non-supplemented formula in the market place”

In conclusion, algal oil (≥36% DHA), in combination with a safe and suitable source of ARA, is not expected to adversely impact the preterm and term infants who would be consuming exempt and non-exempt infant formulae, respectively.

References

Birch EE, Carlson SE, Hoffman DR, Fitzgerald-Gustafson KM, Fu VL, Drover JR, Castañeda YS, Minns L, Wheaton DK, Mundy D, Marunycz J, Diersen-Schade DA. The DIAMOND (DHA Intake And Measurement Of Neural Development) Study: a double-masked, randomized controlled clinical trial of the maturation of infant visual acuity as a function of the dietary level of docosahexaenoic acid. Am J Clin Nutr. 2010;91(4):848-59.

Burks W, Jones SM, Berseth CL, Harris C, Sampson HA, Scalabrin DM. Hypoallergenicity and effects on growth and tolerance of a new amino acid-based formula with docosahexaenoic acid and arachidonic acid. J Pediatr. 2008;153(2):266-71.

Clandinin MT, Van Aerde JE, Merkel KL, et al. Growth and development of preterm infants fed infant formulas containing docosahexaenoic acid and arachidonic acid. J Pediatr. 2005;146(4):461-8.

D'Vaz N, Meldrum SJ, Dunstan JA, Martino D, McCarthy S, Metcalfe J, Tulic MK, Mori TA, Prescott SL. Postnatal fish oil supplementation in high-risk infants to prevent allergy: randomized controlled trial. Pediatrics. 2012;130(4): 674-82.

Fang PC, Kuo HK, Huang CB, et al. The effect of supplementation of docosahexaenoic acid and arachidonic acid on visual acuity and neurodevelopment in larger preterm infants. Chang Gung Med J. 2005;28(10):708-15.

Fleddermann M, Demmelmair H, Grote V, Nikolic T, Trisic B, Koletzko B. Infant formula composition affects energetic efficiency for growth: the BeMIM study, a randomized controlled trial. Clin Nutr. 2014;33(4):588-95.

FDA. 2011a. GRN 000379. Tuna oil, filed by Ocean Nutrition Canada Ltd. Date of closure, Nov. 8, 2011. Available at http://wayback.archive-it.org/7993/20171031045353/https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM276115.pdf.

FDA. 2011b. Agency response Letter to a petition, filed by Cornucopia Institute, Docket No. FDA-2008-P-0074. Available at https://www.regulations.gov/document?D=FDA-2008-P-0074-0017.

FDA. 2015. GRN 000553. Algal oil (40% docosahexaenoic acid) derived from *Schizochytrium* sp., filed by DSM Nutritional Products. Date of closure, June 19, 2015. Available at http://wayback.archive-it.org/7993/20171031040128/https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM456952.pdf.

FDA. 2017. GRAS Notice No. GRN000677. Docosahexaenoic acid oil produced in *Schizochytrium* sp., filed by Mara Renewables Corporation. Date of closure, May 2, 2017. Available at https://www.fda.gov/media/101431/download.

Gunaratne AW, Makrides M, Collins CT, Gibson RA, McPhee AJ, Sullivan TR, Gould JF, Green TJ, Doyle LW, Davis PG, French NP, Colditz PB, Simmer K, Morris SA, Best KP. Docosahexaenoic acid supplementation of preterm infants and parent-reported symptoms of allergic disease at 7 years corrected age: follow-up of a randomized controlled trial. Am J Clin Nutr. 2019;109(6):1600-10.

Hoffman D, Ziegler E, Mitmesser SH, Harris CL, Diersen-Schade DA. Soy-based infant formula supplemented with DHA and ARA supports growth and increases circulating levels of these fatty acids in infants. Lipids. 2008;43(1):29-35.

Manley BJ, Makrides M, Collins CT, McPhee AJ, Gibson RA, Ryan P, Sullivan TR, Davis PG; DINO Steering Committee. High-dose docosahexaenoic acid supplementation of preterm infants: respiratory and allergy outcomes. Pediatrics. 2011;128(1):e71-7.

Vanderhoof JA. Hypoallergenicity and effects on growth and tolerance of a new amino acid-based formula with DHA and ARA. J Pediatr Gastroenterol Nutr. 2008;47 Suppl 2:S60-1.

We hope that the information above responds fully to FDA's follow-up question number 17 regarding GRAS Notification 933. We would be happy to provide you with any further information you may need.

Sincerely,

Susan Cho
NutraSource, Inc. (new company name, AceOne RS)
Susanscho1@yahoo.com or scho@aceoners.com
(301) 875-6454

From:	Susan S Cho
To:	Morissette, Rachel
Subject:	Re: literature review for GRN 000933
Date:	Friday, November 13, 2020 11:47:56 AM
Attachments:	image001.png

Dear Dr. Morrisette,

Initially, we reviewed the literature published between June 2017 and December 2019 for the original submission. However, However, while preparing our responses, we updated the literature review to cover literature published until August 31, 2020. I hope we properly answered your question. Thank you. Have a nice day!

Regards,
Susan
Susan Cho, Ph.D.
AceOne RS,
410-531-3336 (O) 301-875-6454 (MP)

On Friday, November 13, 2020, 10:37:48 AM EST, Morissette, Rachel <rachel.morissette@fda.hhs.gov> wrote:

Dear Dr. Cho,

Can you please confirm as soon as possible the date range of the literature search conducted for GRN 000933?

Best regards,

Rachel

Rachel Morissette, Ph.D.
Regulatory Review Scientist

Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
rachel.morissette@fda.hhs.gov