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

#860

May 3, 2019

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, 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.

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,

[redacted] 5/3/2019

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

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

Prepared for Hubei Fuxing BioTechnology, Co., Ltd

Prepared by: 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 'Fuxing') submits a Generally Recognized as Safe (GRAS) notice and claims that the use of docosahexaenoic acid (DHA) 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: Fuxing 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, 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) Select conventional foods

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 fish oil concentrate (GRN 105), algal oil derived from *Schizochytrium* sp. (GRN 137), and algal oil derived from *Ulkenia* sp. (GRN 319) 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 Fuxing does not intend to use its DHA-rich oil in egg, meat, poultry, and fish products which are included in 21 CFR 184.1472(a)(3).

(2) Infant formulas

DHA-rich oil will also be used as a nutritional food ingredient in exempt (preterm) and non-exempt (term) infant formulas (soy-, whey-, milk-, amino acid-, or hydrolyzed protein-based formulas; ages from birth to 12 months), in combination with a source of arachidonic acid (ARA).

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

Select Conventional Foods

As shown in Table 1, Fuxing intends for DHA-rich oil (containing ≥36% DHA) to be used in the same food categories as those listed in 21 CFR 184.1472(a)(3) (menhaden oil), except in egg, meat, poultry, and fish products, at maximum use levels that are 27.775% 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	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	3.34
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)	7.5	2.08
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	01.11

[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 in 21 CFR 184.1472(a)(3).

Infant Formula

Fuxing intends to market DHA-rich oil, produced from *Schizochytrium* sp., as a direct ingredient in preterm and term infant formulas (soy-, whey-, milk-, amino acid-, or hydrolyzed protein-based formulas; ages from birth to 12 months) in combination with a safe and suitable source of ARA. The intended use level of DHA-rich oil is similar to or same as all other approved uses for incorporation of DHA in infant formula (GRNs 553, 667, 730, and 776). DHA-rich oil may be used at a maximum use level of 1.39% of dietary fat since it has ≥36% DHA. This level corresponds to a maximum of 0.5% of total fat as 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 or DHA-rich oil in infant formula (GRN 553 - stamped page 12; GRN 677 - page 6; GRN 731 - page 5; GRN 776 - page 3; GRN 777 - page 3).

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

The substance will be used as a nutritional ingredient in selected foods and in term and preterm infant formulas.

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

The population expected to consume the substance consists of members of the general population who consume at least one of the products described above, and preterm and 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 Susan Cho at NutraSource, Inc. 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: May 3, 2019
Title: Export Manager

Address correspondence to
Susan S. Cho, Ph.D., NutraSource, Inc.
Agent for Fuxing

1.I. FSIS/USDA Statement

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.

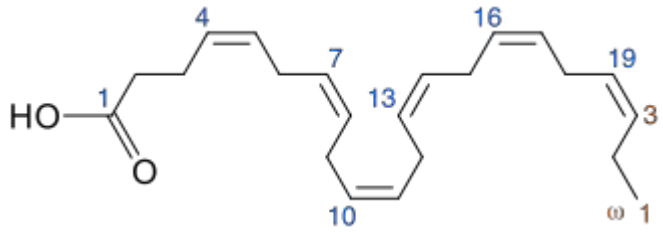


Figure 1. Structure of DHA

2.A.1.7. Physical Properties

Density, 0.943 g/cm^3

2.A.1.8. Background

Docosahexaenoic acid (DHA) is an omega-3 fatty acid (FA) that is a primary structural component of the human brain, retina, and other tissues. It can be synthesized from alpha-linolenic acid or obtained directly from maternal milk, algal oil, or fish oil. Fatty acids can be desaturated endogenously up to the Δ9 position due to the lack of certain enzymes in humans (Kremmyda et al., 2011). For this reason, linoleic (18:2n-6) and α-linolenic (18:3n-3) acids must be obtained from the diet and are termed as essential FAs. Further elongation and desaturation of these FA to produce long-chain polyunsaturated fatty acids (PUFA) is possible but not very

efficient in humans. Examples of PUFA include arachidonic acids (ARA; 20:4n-6), eicosapentaenoic (EPA; 20:5n-3), and DHA (22:6n-3). Thus, these FAs may be conditionally essential depending on essential FA availability.

Fuxing's DHA-rich oil is derived from the heterotrophic fermentation of the marine alga, *Schizochytrium* sp. strain DHF. DHA's structure is a carboxylic acid with a 22-carbon chain *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.

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

Potential toxicants have not been identified in Fuxing's DHA-rich oil. High-performance liquid chromatography (HPLC) reveals that Fuxing's DHA-rich oil is ≥36.0% pure with an average of 39.4%. No significant amounts of solvent residues, polycyclic aromatic hydrocarbons (PAHs), polychlorinated biphenyls **(**PCBs), dioxins and furans, pesticides, domoic acid, or mycotoxins have been detected in Fuxing's DHA-rich oil (Tables 2 to 8 and Appendix A). The Certificates of Analysis (COA) for DHA-rich oil are presented in Appendix A (a pdf file).

Solvent Residues

As shown in Table 2, no significant amounts of residual solvents were detected in DHA-rich oil as no organic solvents are used to extract the DHA-rich oil from the fermentation biomass.

PAHs, PCBs, Dioxins and Furans and Pesticides

The analysis of 5 non-consecutive lots of DHA-rich algal oil samples found that concentrations of PAHs, PCBs, dioxins and furans, and pesticides (including selected organochlorine and organophosphorus pesticides) were at levels below or close to the detection limits (Tables 3 to 6; Certificates of Analysis are shown in Appendix A).

Shellfish Poison and Mycotoxins

No amnesic shellfish poison (domoic acid) and mycotoxins (fumonosins, aflatoxins, ochratoxin A, zearalenone, or vomitoxin) were detected from Fuxing's DHA-rich oil (Tables 7 and 8).

Table 2. A List of Solvent Residues Tested for DHA

Parameters, mg/kg	Lot Numbers					Mean
	D1807 1101J	D1808 1801J	D1811 1401J	D1812 2601J	D1812 2701J	
1,1,1-Tichloroethane	<0.2	<0.2	<0.2	<0.2	<0.2	<0.2
1,1,2-Tichloroethane	<0.2	<0.2	<0.2	<0.2	<0.2	<0.2
1,2-Dichloroethane	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5
1,2-Dimethoxyethane	<1	<1	<1	<1	<1	<1
1-Butanol	<1	<1	<1	<1	<1	<1
2-Hexanone	<1	<1	<1	<1	<1	<1
Acetone	<1	<1	<1	<1	<1	<1

Benzene	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Butyl acetate	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5
Carbon tetrachloride	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5
Chlorobenzene	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5
Chloroform	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Cyclohexane	<0.2	<0.2	<0.2	<0.2	<0.2	<0.2
Dichloromethane	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Ethanol	<1	<1	<1	<1	<1	<1
Ethyl acetate	<1	<1	<1	<1	<1	<1
Heptane	<0.2	<0.2	<0.2	<0.2	<0.2	<0.2
Hexane (sum of n-hexane, iso and 3-methyl pentane)	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5
Isopropanol	<1	<1	<1	<1	<1	<1
Methanol	<1	<1	<1	<1	<1	<1
Methyl ethyl ketone	<0.2	<0.2	<0.2	<0.2	<0.2	<0.2
Methyl-tert-butylether	<0.2	<0.2	<0.2	<0.2	<0.2	<0.2
Tetralin	<5	<5	<5	<5	<5	<5
Toluene	<0.2	<0.2	<0.2	<0.2	<0.2	<0.2
Trichloroethylene	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Xylenes (sum)	<0.2	<0.2	<0.2	<0.2	<0.2	<0.2

Table 3. Analysis of PAHs for DHA-Rich Oil

Parameters, µg/kg	Lot Numbers					Mean
	D1807 1101J	D1808 1801J	D1811 1401J	D1812 2601J	D1812 2701J	
5-Methylchrysene	<1	<1	<1	<1	<1	<1
Benz(a)anthracene	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5
Benzo(a)pyrene	<0.5	<0.5	<0.5	<0.5	0.8	<0.6
Benzo(b)fluoranthene	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5
Benzo-(c)-fluorene	<1	<1	<1	<1	1.6	<1.1
Benzo(g,h,i)perylene	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5
Benzo-(j)-fluoranthene	<0.5	<0.5	<0.5	0.6	<0.5	<0.5
Benzo(k)fluoranthene	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5
Chrysene	<0.5	<0.5	<0.5	<0.5	0.7	<0.5
Cyclopenta(c,d)pyrene	<1	<1	<1	<1	<1	<1
Dibenz(a,h)anthracene	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5
Dibenzo(a,e)pyrene	<1	<1	<1	<1	<1	<1
Dibenzo(a,h)pyrene	<1	<1	<1	<1	<1	<1
Dibenzo(a,i)pyrene	<1	<1	<1	<1	<1	<1
Dibenzo(a,l)pyrene	<1	<1	<1	<1	<1	<1
Indeno(1,2,3-cd)pyrene	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5

Sum of all positive identified PAH	In-applicable	In-applicable	In-applicable	0.6	3.1	
Sum of PAH 4				In-applicable	1.5	

Table 4. Analysis of PCBs for DHA-Rich Oil

Parameters, mg/kg	Lot Numbers					Mean
	D1807 1101J	D1808 1801J	D1811 1401J	D1812 2601J	D1812 2701J	
PCB 1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 101	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 104	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 105	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 118	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 126	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 128	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 138	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 153	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 170	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 18	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 180	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 187	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 188	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 195	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 201	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 206	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 209	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 28	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 29	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 44	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 50	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 52	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 66	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 77	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 8	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
PCB 87	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Sum Non-Dioxin-Like PCBs (28+52+101+ 138+153+ 180)	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Total PCB	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1

Table 5. List of Dioxins and Furans Tested for DHA-Rich Oil

Dioxins and Furans, pg/g	D18071101J	D18111401J	D18122701J
1,2,3,4,6,7,8-HeptaCDD	<0.130	<0.131	<0.126
1,2,3,4,6,7,8-HeptaCDF	<0.0912	<0.0914	<0.0881
1,2,3,4,7,8,9-HeptaCDF	<0.0635	<0.0636	<0.0613
1,2,3,4,7,8-HexaCDD	<0.0619	<0.0620	<0.0597
1,2,3,4,7,8-HexaCDF	<0.0961	<0.0962	<0.0928
1,2,3,6,7,8-HexaCDD	<0.0847	<0.0848	<0.0818
1,2,3,6,7,8-HexaCDF	<0.0879	<0.0881	<0.0849
1,2,3,7,8,9-HexaCDD	<0.0798	<0.0799	<0.0770
1,2,3,7,8,9-HexaCDF	<0.0651	<0.0653	<0.0629
1,2,3,7,8-PentaCDD	<0.0407	<0.0408	<0.0393
1,2,3,7,8-PentaCDF	<0.0586	<0.0587	<0.0566
2,3,4,6,7,8-HexaCDF	<0.0798	<0.0799	<0.0770
2,3,4,7,8-PentaCDF	<0.0912	<0.0914	<0.0881
2,3,7,8-TetraCDD	<0.0309	<0.0310	<0.0299
2,3,7,8-TetraCDF	<0.0847	<0.0848	<0.0818
OctaCDD	<0.945	<0.946	<0.912
OctaCDF	<0.195	<0.196	<0.189
WHO(2005)-PCDD/F TEQ (lower-bound)	Not Detected	Not Detected	Not Detected
WHO(2005)-PCDD/F TEQ (medium-bound)	0.0840	0.0841	0.0811
WHO(2005)-PCDD/F TEQ (upper-bound)	0.168	0.168	0.162

Table 6. List of Pesticides Screened for DHA-Rich Oil

Pesticide (LOQ, mg/kg)	Pesticide (LOQ, mg/kg)	Pesticide (LOQ, mg/kg)
2-Phenylphenol (0.01)	Acetochlor (0.06)	Aclonifen (0.05)
Aldrin (0.01)	Ametryne (0.02)	Aramite (0.04)
Atrazine (0.02)	Benfluralin (0.01)	Bifenox (0.05)
Bifenthrin (0.01)	Biphenyl (0.01)	Bromfenvinphos (0.02)
Bromophos (0.01)	Bromophos-ethyl (0.01)	Bromopropylate (0.01)
Butachlor (0.01)	Butafenacil (0.01)	Cadusafos (0.02)
Captafol (0.06)	Captan (0.06)	Captan/THPI (sum calculated as Captan)
Carbophenothion (0.05)	Carbophenothion-methyl (0.05)	Carboxin (0.06)
Chlorbenside (0.06)	Chlordane (sum)	Chlordane, alpha (0.01)
Chlordane, gamma (0.01)	Chlorfenapry (0.05)	Chlorfenson (0.05)
Chlorfenvinphos (0.01)	Chlormephos (0.05)	Chlorobenzilate (0.01)
Chloroneb (0.01)	Chloropropylate (0.01)	Chlorothalonil (0.01)
Chlorpyrifos (-ethyl) (0.01)	Chlorpyrifos-methyl (0.01)	Chlorthal-dimethyl (0.01)

Chlorthion (0.05)	Chlozolinate (0.02)	Crufomate (0.05)
Cyanazine (0.02)	Cyanofenphos (0.05)	Cyanophos (0.02)
Cyfluthrin (0.05)	Cyhalothrin, lamda- (0.01)	Cypermethrin (0.05)
Cyphenothrin (0.05)	DDD, o,p'- (0.01)	DDD, p,p'- (0.01)
DDE, o,p- (0.01)	DDE, p,p'- (0.01)	DDT (sum)
DDT, o,p'- (0.01)	DDT, p,p'- (0.01)	Deltamethrin (0.05)
Dichlobenil (0.05)	Dichlofenthion (0.02)	Dichlofluanid (0.02)
Dichlorobenzophenone o,p' (0.02)	Dichlorobenzophenone p,p' (0.02)	Dichlorvos (0.05)
Dicloran (0.05)	Dicofol (sum)	Dicofol, o,p'- (0.02)
Dicofol, p,p'- (0.02)	Dieldrin (0.02)	Dieldrin (sum)
Dienochlor (0.05)	Dinobuton (0.05)	Dioxabenzofos (0.02)
Dioxathion (0.05)	Diphenylamine (0.01)	Edifenphos (0.02)
Endosulfan (sum) ()	Endosulfan, alpha- (0.05)	Endosulfan, beta- (0.05)
Endosulfan, sulfat- (0.02)	Endrin (0.05)	EPN (0.05)
Ethalfluralin (0.01)	Ethion (0.02)	Etridiazole (0.02)
Etrimfos (0.02)	Fenamiphos (0.05)	Fenchlorphos (0.02)
Fenchlorphos (sum)	Fenchlorphos oxon (0.01)	Fenfluthrin (0.01)
Fenitrothion (0.02)	Fenpropathrin (0.02)	Fenson (0.02)
Fenthion (0.02)	Fenvalerate & Esfenvalerate (sum of RS & SR isomers) (0.02)	Fenvalerate & Esfenvalerate (sum of RR, SS, RS, SR) ()
Fenvalerate & Esfenvalerate (sum of RR & SS isomers) (0.02)	Fluchloralin (0.05)	Flucythrinate (0.05)
Flumetralin (0.05)	Fluotrimazole (0.01)	Fluquinconazole (0.02)
Fluvalinate-tau (0.02)	Fonofos (0.02)	Formothion (0.05)
HCB (0.01)	HCH gamma(Lindan) (0.01)	HCH, alpha- (0.01)
HCH, beta- (0.01)	HCH, delta- (0.01)	HCH, epsilon- (0.01)
Heptachlor (0.01)	Heptachlor (sum) ()	Heptachlor epoxide cis (0.01)
Heptachlor epoxide trans (0.01)	Heptenophos (0.02)	Iprobenfos (0.02)
Isazophos (0.01)	Isocarbofos (0.02)	Isodrin (0.02)
Isofenphos (0.02)	Isofenphos-methyl (0.01)	Isoprothiolane (0.02)
Jodfenphos (0.02)	Kresoxim-methyl (0.01)	Landrin (0.02)
Malaoxon (0.05)	Malathion (0.02)	Malathion (sum) ()
Mecarbam (0.04)	Mepronil (0.01)	Methacriphos (0.02)
Methamidophos (0.1)	Methidathion (0.02)	Methoxychlor (0.02)
Methyl-Pentachlorophenylsulfide (0.06)	Metribuzin (0.04)	Mevinphos (0.02)
Mirex (0.01)	N-Desethyl-pirimiphos-methyl (0.01)	Nitrapyrin (0.01)
Nitrofen (0.02)	Nitrothal-isopropyl (0.01)	Octachlorodipropyl ether (S 421) (0.05)

Ofurace (0.01)	Oxadiazon (0.02)	Oxychlordane (0.02)
Oxyfluorfen (0.02)	Paclobutrazol (0.01)	Parathion (0.01)
Parathion-methyl (0.04)	PCB 101 (0.01)	PCB 138 (0.01)
PCB 153 (0.01)	PCB 180 (0.01)	PCB 28 (0.01)
PCB 52 (0.01)	Pentachloranisole (0.01)	Pentachloroaniline (0.01)
Pentachlorobenzene (0.01)	Permethrin (0.02)	Phenkapton (0.05)
Phenothrin (0.01)	Phenthoate (0.02)	Phorate (0.04)
Phosphamidon (0.04)	Picoxystrobin (0.01)	Piperophos (0.01)
Pirimiphos-ethyl (0.01)	Procymidone (0.01)	Profenofos (0.01)
Profluralin (0.02)	Prometryn (0.02)	Propanil (0.01)
Propazine (0.01)	Prothiofos (0.02)	Pyrazophos (0.01)
Pyridalyl (0.06)	Pyridaphenthion (0.02)	Pyrifenox (0.04)
Pyrimethanil (0.01)	Quinalphos (0.01)	Quintozene (0.01)
Quizalofop-P-ethyl (0.01)	Silafluofen (0.06)	Silthiofam (0.01)
Tebufenpyrad (0.01)	Tecnazene (0.02)	Tefluthrin (0.02)
Terbufos (0.02)	Tetrachlorvinphos (0.02)	Tetradifon (0.02)
Tetrahydrophthalimide (THPI) (0.06)	Tetramethrin (0.02)	Tetrasul (0.01)
Tolyfluanid (0.02)	Triallate (0.02)	Triazamate (0.01)
Triazophos (0.02)	Trichloronat (0.01)	Trifluralin (0.02)
Triticonazole (0.01)	Uniconazole (0.02)	Vinclozolin (0.02)

Blue and purple fonts indicate organochlorine and organophosphorus pesticides, respectively.

Table 7. Analytical Results for Amnesic Shellfish Poison

Amnesic Shellfish Poison, Domoic Acid, ug/g	D1807 1101J	D1808 1801J	D1811 1401J	D1812 2601J	D1812 2701J
Detection limit	< 3.0	< 3.0	< 3.0	< 3.0	< 3.0
Results	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected

Table 8. Analysis of Mycotoxins for DHA-Rich Oil

Parameters, µg/kg	Lot Numbers					Mean
	D1807 1101J	D1808 1801J	D1811 1401J	D1812 2601J	D1812 2701J	
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	<0.4
Vomitoxin (Deoxynivalenol)	<50	<50	<50	<50	<50	<50
Ochratoxin A	<1	<1	<1	<1	<1	<1
Zearalenone	<25	<25	<25	<25	<25	<25

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 NaOH 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, potassium sulfate, corn syrup powder (corn steep liquor), malic acid, sodium hydroxide, and citric acid.

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 (source: Novozyme Alcalase 2.4 L FG; 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, EDTA, and water), deacidification (sodium hydroxide), decolorization (nitrogen, activated carbon, and activate clay at 70 to 90°C for 45 to 60 minutes), filtration, and deodorization (at 190 to 210°C and -230 pa for 1.5 to 3.5 hours).

Packaging

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

Table 9. Raw Materials Used in Fermentation

Ingredient	CAS number	Regulatory status
Yeast extract	8013-01-2	21CFR 172.896
Glucose	50-99-7	21 CFR 168.121
Potassium sulfate	7778-80-5	21CFR 184.1643
Corn syrup powder (corn steep liquor)	66071-94-1	21CFR 184.1033
Malic acid	97-67-6	21CFR 184.1069
Sodium hydroxide	1310-73-2	21CFR 184.1763
Citric acid	5959-29-1	21CFR 184.1033

Table 10. Processing Aids

Processing aids	CAS number	Regulatory status
Tocopherols	1406-66-2	21CFR 184.1890
Activated clay	1302-78-9	21CFR 184.1155
Activated carbon	14808-60-7	21CFR 170.30 (c)(1)
Ascorbyl palmitate	137-66-6	21CFR 182.3149
Citric acid monohydrate	5959-29-1	21CFR 184.1033
Sodium hydroxide	1310-73-2	21CFR 184.1763

Manufacturing process of the DHA-rich oil meets current Good Manufacturing Practice (cGMP) requirements for the production of food. All growth media, raw materials, and processing aids used in the DHA fermentation and manufacturing processes meet internationally recognized specification requirements for food production. The fermentation process is well-controlled and 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 well-defined product specifications prior to release.

DHA-rich oil (Fuxing)

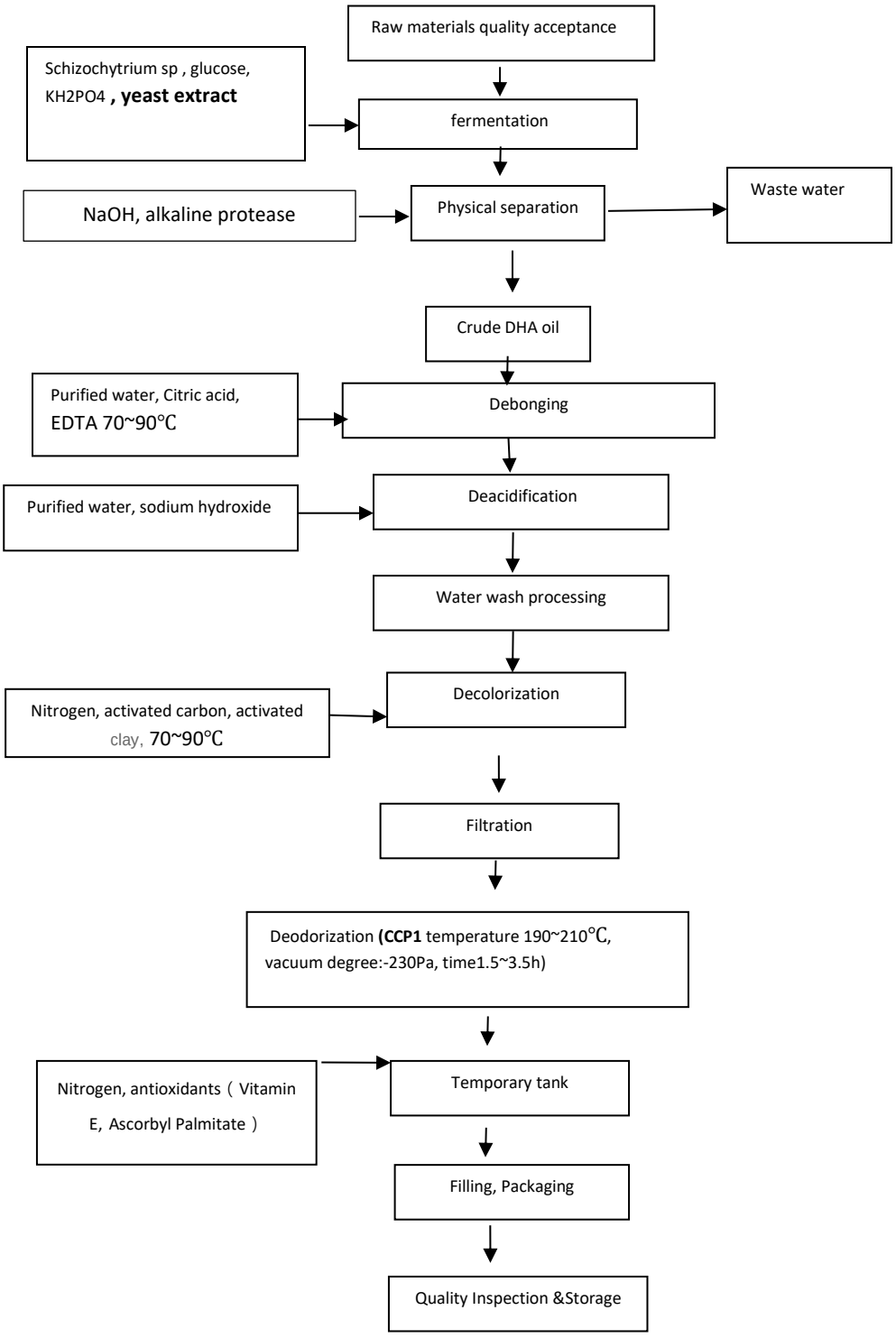


Figure 2. Manufacturing Flow Diagram of DHA-Rich Oil

Characterization of the Production Microorganism

The principle of the production method (via algal production) 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, 2004a; 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, China Center for Type Culture Collection (CCTCC) identified Fuxing's strain DHF as *Schizochytrium* sp. *Schizochytrium* sp. is a thraustochytrid and a member of the Chromista kingdom (Appendix B). 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 consumption of mussels and clams. Indirect consumption, through the marine food chain (fish and shellfish), is more widespread. Analysis of the finished products confirmed the absence of common shellfish toxins. *Schizochytrium* sp. microorganisms are widespread and are commonly found in marine environments throughout the world. There have never been any reports of toxic compounds produced by these microorganisms. Taxonomic Classification of *Schizochytrium* sp. is presented in Table 11.

Table 11. 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.

2.C. Specifications and Composition

Table 12 presents the specifications of Fuxing's DHA-rich oil in comparison with those described in GRNs 137 (page 21, stamped page 26), 553 (page 17, stamped page 23), 677 (page 15), 731/732 (page 17/page 19), 776 (page 10) and 777 (page 10). Table 13 summarizes the analytical values for 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 to ensure that Fuxing's DHA-rich oil products meet the specifications and are free from contaminations. DHA-rich oil is a free flowing, yellow oil.

Tables 14 and 15 show the FA profiles of Fuxing's DHA-rich oil in comparison with those described in GRNs 137 (page 24, stamped page 29), 553 (page 18, stamped page 29), 677 (page 20), 731/ 732 (page 20/page 21), and 776/777 (both on page 12). The DHA content is comparable to those described in previous GRAS notices (current notice vs. GRN 137 vs. GRN 553 vs. GRN 667 vs. GRN 730/731 vs. GRN 776: ≥36% vs. 32-45 vs. ≥35% vs. ≥35% vs. ≥45% vs. ≥35%). The fatty acid profiles of these oils are similar to each other: palmitic acid and docosapentaenoic acid (DPA) are predominant fatty acids, next to DHA (Tables 14 and 15).

Table 12. Specifications of DHA-Rich Oil

Parameter	Specifications							Method of Analysis for the Current Notice
	Current notice	GRN 137[a]	GRN 553[b]	GRN 667[b]	GRN 731[b] & 732[c]	GRN 776[b]	GRN 777[b]	
DHA, %	≥36	32 - 45	≥35	>35	≥45	≥35	≥55	AOCS Ce 2-66 AOCS Ce 1-62
Acid value, mg KOH/g	≤ 0.5	<0.5	<0.5	<0.5	< 0.5	<0.5	<0.5	AOCS Cd 3d-63
Free fatty acid, as % oleic acid	≤ 0.4	NA	<0.4	NA	< 0.1			AOCS Ca 5a-40
Trans fatty acids, %	≤1.0	<2.0	<3.5	NA	<1.0	<1	<1	AOCA Ce 1f-96
Unsaponifiable matter, %	≤3.0	<4.5	<3.5	<3.5	<3.0	<3.5	<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 8b-53
Moisture (direct drying method), wt%	≤0.1	<0.1	< 0.02	< 0.05	<0.1	<0.05	<0.05	AOCS Ca 2e-84
Docosapentaenoic acid (DPA, n-6), %	≤15	10-20			NA			AOCS Ce 2-66 AOCS Ce 1-62
Copper, ppm	≤0.1	<0.1	<0.1	<0.1	<0.1	<0.05	<0.05	BS EN ISO 17294-2 2016 mod. except Iron - Eurofin internal method ICP-OES, ICO-OES
Iron, ppm	≤0.1	<0.5	<0.2	<0.2	<0.5	<0.2	<0.2	
Lead, ppm	≤0.1	<0.2	< 0.1	< 0.1	< 0.1	<0.01	<0.01	
Arsenic, ppm	≤ 0.1	<0.5	< 0.1	< 0.1	< 0.1	<0.1	<0.1	
Cadmium, ppm	≤0.1		< 0.1	NA	< 0.1	<0.01	<0.01	
Mercury, ppm	≤0.04	<0.2	< 0.04	< 0.1	< 0.04	<0.04	<0.04	BS EN 13806:2002
Coliforms, cfu/ml	≤10	NA	< 1	NA	< 1	<10 MPN/g	<10	AOAC 991.14
Molds, cfu/ml	≤10	NA	< 1	NA	< 1	<100	<100	AOAC 997.02
Yeast, cfu/ml	≤10	NA	< 1	NA	< 1	<100	<100	
Salmonella/25 g	Not Detected	NA	Not Detected	NA	Not Detected			AOAC-RI 121501

*Total FFA; 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; MPN=most probable number. [a]DHA-rich oil derived from *C. cohnii* for selected general food application; [b]DHA-rich oil derived from *Scizochytrium* sp. for infant formula application; [c]DHA-rich oil derived from *Scizochytrium* sp. for selected general food application.

Table 13. Summary of Analytical Values for Fuxing's DHA-Rich Oil*

Parameter	Analytical values supporting specifications					Mean
	D18071 101J	D18081 801J	D18111 401J	D18122 601J	D18122 701J	
DHA, %	38.24	38.06	38.78	38.30	43.48	39.37
Acid value, mg KOH/g	0.52	0.34	0.38	0.38	0.60	0.44
Free fatty acid, as % oleic acid	0.26	0.17	0.19	0.19	0.30	0.22
Trans fatty acids, %	0.20	0.12	0.15	<0.01	<0.01	<0.16
Unsaponifiable matter, %	1.66	1.04	1.58	1.03	1.95	1.45
Peroxide value, meq/kg	<0.1	2.1	<0.1	1.1	<0.1	<0.7
Moisture, g/100 g	0.02	0.02	0.02	0.01		0.02
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	<0.1	<0.1
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	<10
Molds, cfu/ml	<10	<10	<10	<10	<10	<10
Yeast, cfu/ml	<10	<10	<10	<10	<10	<10
Salmonella, /25 g	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected

*Samples were taken from 5 non-consecutive batches.

Table 14. Fatty Acid Profile of Fuxing's DHA-Rich Oil

Parameters, %	Lot Numbers					Mean
	D1807 1101J	D1808 1801J	D1811 1401J	D1812 2601J	D1812 2701J	
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	0.05	0.08
C14:0 Tetradecenoic (Myristic)	0.46	2.60	0.46	2.59	0.43	1.31
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	1.13	1.07
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	21.67	27.12
C16:1 Hexadecenoic (Palmitoleic)	0.15	0.27	0.13	0.28	0.13	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	1.53	0.87
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	1.13	1.13
C18:1 Octadecenoic (Oleic + isomers)	3.25	0.44	3.29	0.44	1.07	1.70
C18:2 Octadecadienoic (Linoleic + isomers)	6.84	0.85	6.99	0.84	2.50	3.60
C18:2 Octadecadienoic Omega 6 (Linoleic)	6.82	0.77	6.88	0.78	2.45	3.54
C18:3 Octadecatrienoic (Linolenic + isomers)	0.84	0.19	0.91	0.19	0.53	0.53
C18:3 Octadecatrienoic Omega 3 (Alpha Linolenic)	0.75	0.13	0.76	0.13	0.36	0.43
C18:3 Octadecatrienoic Omega 6 (Gamma Linolenic)	0.10	0.07	0.15	0.06	0.17	0.11
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	0.24	0.21
C20:1 Eicosenoic (Gondoic + isomers)	0.03	<0.02	0.06	<0.02	0.03	<0.03
C20:2 Eicosadienoic Omega 6	0.03	<0.02	0.04	<0.02	0.02	<0.03
C20:3 Eicosatrienoic	0.22	0.15	0.23	0.11	0.21	0.18
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	0.21	0.17
C20:4 Eicosatetraenoic (Arachidonic + isomers)	0.90	2.20	1.09	2.24	0.65	1.42
C20:4 Eicosatetraenoic Omega 3	0.49	0.48	0.50	0.50	0.55	0.50
C20:4 Eicosatetraenoic Omega 6 (Arachidonic)	0.41	1.72	0.59	1.74	0.09	0.91
C20:5 Eicosapentaenoic Omega 3	0.19	0.40	0.23	0.46	0.33	0.32
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	0.13	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	0.05	0.04
C22:5 Docosapentaenoic	10.62	4.92	10.96	5.10	11.80	8.68
C22:5 Docosapentaenoic Omega 3	0.05	0.09	0.06	0.11	0.15	0.09
C22:5 Docosapentaenoic Omega 6	10.58	4.83	10.90	4.99	11.65	8.59
C22:6 Docosahexaenoic Omega 3	**38.24**	**38.06**	**38.78**	**38.30**	**43.48**	**39.37**
C24:0 Tetracosanoic (Lignoceric)	<0.02	<0.02	0.15	0.06	0.07	<0.06
C24:1 Tetracosenoic (Nervonic)	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
Sum of Omega 3 Isomers	39.82	39.37	40.45	39.67	45.00	40.86
Sum of Omega 6 Isomers	18.21	7.52	18.85	7.71	14.65	13.38
Total Fat as Triglycerides	91.43	92.31	93.15	92.76	91.07	92.14
Total Fatty Acids Calc.	87.69	88.42	89.35	88.85	87.38	88.34
Total Monounsaturated Fatty Acids	3.48	1.25	3.50	0.80	1.26	2.06
Total Polyunsaturated Fatty Acids	58.06	46.96	59.40	47.44	59.72	54.32
Total Saturated Fatty Acids	26.16	40.22	26.44	40.61	26.41	31.97

Table 15. Comparison of Fatty Acid Profiles of DHA-Rich Oils

	Current notice	GRN 137[a]	GRN 553[b]	GRN 677[b]	GRN 731[b] & 732[c]	GRN 776[b]	GRN 777[b]
DHA (Docosahexaenoic acid) specifications, %	**≥36**	**32 - 45**	**≥35**	**≥35**	**≥45**	**≥35**	**≥55**
Actual content, %	39.4		43.3		50.7	38.2	61.1
Fatty Acid Profile, g/100g							
C 6:0 (Caproic acid)			NA	NA	< 0.02		
C 8:0 (Caprylic acid)	<0.02		NA	NA	< 0.02		
C 10:0 (Capric acid)	<0.02		NA	NA	< 0.02		
C 12:0 (Lauric acid)	0.08	0.04	<0.10	0.91	0.10	0.2	0.10
C 14:0 (Myristic acid)	1.31	10.11	1.18	11.87	0.82	4.0	1.27
C 14:1 (Myristoleic acid)	<0.12		<0.10	<0.10	< 0.02		0.37
C 15:0 (Pentadecanoic acid)	1.07		0.24	0.52	0.06		0.10
C 15:1 (Pentadecenoic acid)	<0.02		NA	NA	0.07		
C 16:0 (Palmitic acid)	27.12	23.68	13.78	25.43	20.96	44.7	20.57
C 16:1 (Palmitoleic acid)	0.19	1.76	<0.10	3.42	0.51		0.30
C 17:0 (Margaric acid or Heptadecanoic acid)	0.87		<0.10	<0.10-0.15	0.08		0.10
C 18:0 (Stearic acid)	1.13	0.45	1.65	0.82	1.30	1.1	0.77
C 18:1 (Oleic acid)	1.70	NA	25.00	4.77	0.27		0.70
C 18:1n7 (Vaccenic acid)		Trace-1.36	0.26	NA	0.51	-	
C 18:2n6 (Linoleic acid)	3.54		2.01	0.33	< 0.02	0.6	0.13
C 18:3n3 (alpha-Linolenic acid)	0.43		<0.10	NA	0.14		0.20
C 18:3n6 (gamma-Linolenic acid)	0.11		NA	0.23	0.09		0.10
C 20:0 (Arachidic acid)	0.21		0.32	<0.10	0.29		0.10
C 20:1 (Eicosenoic acid)	<0.03		<0.1	<0.01-<0.10	< 0.02		<0.05
C 20:2n6 (Eicosodienoic acid)			0.13	NA	< 0.02		N.D.
C 20:3n3 (Eicosatrienoic acid)			NA	NA	1.34		N.D.
C 20:3n6 (homo-gamma-Linolenic acid)			<0.1	1.18	0.21	0.1	0.13

C 20:4n6 (Arachidonic acid)	0.91	0.94	0.69	NA	0.15	0.3	0.10
C 20:5n3 (Eicosapentaenoic acid; EPA)	0.32	2.63	6.22	NA	0.70	0.2	0.67
C 21:0 (Heneicosanoic acid)			NA	NA	0.04		
C 22:0 (Behenic acid)	0.12		0.35	<0.10	0.15		0.10
C 22:1n9 (Erucic acid)			NA	NA	< 0.02		
C 22:2n6 (Docosadienoic acid)	<0.02		0.53	NA	< 0.02		
C 22-5n3 (Docosapentaenoic acid)	0.09		0.76	NA	0.11	0.2	0.27
C 22-5n6 (Docosapentaenoic acid)	8.59	13.5	2.53	7.81	10.33	7.8	10.50
C 23:0 (Tricosanoic acid)			NA	NA	< 0.02		
C 24:0 (Lignoceric acid)	<0.06		0.14	<0.10	0.15		0.10
C 24:1 (Nervonic acid)	<0.02		<0.10	NA	0.41		0.10

NA= not available; [a]DHA-rich oil derived from *C. cohnii* for selected general food application; [b]DHA-rich oil derived from *Scizochytrium* sp. for infant formula application; [c]DHA-rich oil derived from *Scizochytrium* sp. for selected general food application.

Table 16 summarizes the sterol content in Fuxing's DHA-rich oil. Table 17 presents the sterol content of Fuxing's DHA-rich oil in comparison with those described in GRNs 553 (page 21, stamped page 27), 677 (page 21), and 776 (page 14). As shown in Table 17, the total concentrations of plant sterols and plant stanols of Fuxing's DHA-rich oil are comparable to those described in previous GRAS notices.

Table 16. Plant Sterols and Plant Stanols in Fuxing's DHA-Rich Oil

Parameters, mg/100 g	Lot Numbers					Mean
	D1807 1101J	D1808 1801J	D1811 1401J	D1812 2601J	D1812 2701J	
Brassicasterol	15	9	15	10	22	14
Cholesterol	210	113	210	114	356	201
Campesterol	15	5	15	5	9	10
Campestanol	1	1	1	1	5	2
Stigmasterol	27	10	28	10	40	23
Unidentified sterols	196	115	197	116	235	172
Sitosterol	67	23	68	23	66	49
Sitosterol + delta-5-avenasterol	7	5	8	6	6	6
Delta-5,24-stigmastadienol	10	4	10	3	10	7
Delta-7-stigmastenol	28	13	28	13	31	23
delta-7-Avenasterol	6	1	6	1	5	4
Cycloartenol	2	2	3	2	2	2
24-Methylenecycloartanol	2	3	3	3	1	2
Citrostadienol	2	1	2	1	1	1
Total plant sterols + plant stanols	372	186	375	188	428	310

Table 17. Comparison of Plant Sterols in DHA-Rich Oils

Parameters	Current Notice	GRN 553	GRN 677	GRN 776
Brassicasterol, %	0.014	1.3	<0.1	9.5
Cholesterol, %	0.201	13.3	24.3	33.8
Campesterol, %	0.010	0.1	1.2	0.4
Campestanol, %	0.002	2.0	<0.1	<0.1
Stigmasterol, %	0.023	64.2	<0.1	1.9
Unidentified sterols, %	0.172			
Sitosterol, %	0.049			
Sitosterol + delta-5-avenasterol, %	0.006			
Delta-5,24-stigmastadienol, %	0.007	0.4	7.0	0.7
Delta-7-stigmastenol	0.023	1.7	26.1	1.4
delta-7-Avenasterol, %	0.004	0.3	3.6	0.3
Cycloartenol, %	0.002			
24-Methylenecycloartanol	0.002			
Citrostadienol	0.001			
Total plant sterols + plant stanols	0.31 wt%	0.56 wt%	0.23 wt%	1.01 wt%

Expanded from GRN 776.

2.D. Stability

The stability of 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. Fuxing will recommend product use (best before date) within 1 year of the date of manufacture.

2.E. Intended Technical Effects

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

PART 3. EXPOSURE ESTIMATES

3.A. Intended Use

Select Conventional Foods

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) at maximum use levels that are 27.775% of those specified in that regulation. DHA-rich oil is not to be combined with any other added oil that is a significant source of DHA or EPA. We derived the 27.775% value because of 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. An 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 55.55% (20/36) is needed to accommodate the different concentrations of DHA in the two oils.
3) The 27.775% adjustment is calculated by multiplying the 50% adjustment that is needed in accordance with the first bullet point above by the 55.55% adjustment that is needed in accordance with the second bullet point above, i.e., (0.50) x (0.555) x 100 = 27.775%.

These are the same food categories (except egg, meat, poultry, and fish products) found in the GRAS notification for fish oil concentrate (GRN 105, stamped pages 5 to 6 and page 10) and DHA-algal oils (GRN 137, stamped pages 10 to 12 and 27 to 28 - FDA, 2004a; GRN 319, stamped pages 6 to 7 and page 17- FDA, 2010; GRN 732, page 25 -FDA, 2018b) for which the agency did not raise any objections to the company's conclusion that its fish oil concentrate and DHA-algal oils derived from *Schizochytrium* sp. and *Ulkenia* sp. would be considered GRAS when used in the food categories identified for menhaden oil.

Infant Formulas

The intended use level is similar to all other approved uses for incorporation of algal DHA-rich oils in exempt (preterm) and non-exempt (term) infant formula (GRN 41, stamped page 101 - FDA, 2001; GRN 94, stamped page 3 - FDA, 2006a; GRN 379, stamped page 8 - FDA, 2011b; GRNs 553, stamped page 12 - FDA, 2015; GRN 677, page 6 - FDA, 2017; GRN 731, page 5 - FDA, 2018a; GRN 776, page 3 - FDA, 2018c; GRN 777, page 3 - FDA, 2018d). DHA-rich oil may be used at a maximum use level of 1.39% of total dietary fat since it has ≥36% DHA. This level corresponds to a maximum of 0.5% of total dietary fat as DHA. The ratio of DHA to ARA would range from 1:1 to 1:2.

3.B. Exposure Estimates

For Select Conventional Food Applications

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. In GRN 137, the estimate exposure at the intended use levels is 1.4 g/person/day from the current intended use levels (which was indicated as the future use levels at that time). 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.

DHA-rich oil is intended to be the sole source of DHA in any given food category. It would be possible, however, to blend DHA-rich oil with other sources of DHA and/or EPA. FDA has determined in its review of other sources of DHA and/or EPA that these oils may be used at a level providing up to 3.0 g of DHA and/or EPA per day. In the event that a manufacturer blends DHA-rich oil with another oil that is a source of DHA and/or EPA, such blending would be appropriate provided that (1) the DHA-rich oil is used at a level consistent with Table 1 and its use would not result in more than 1.5 g of DHA/person/day and (2) the other oil source of DHA and/or EPA is used at a level that would not result in a cumulative exposure of DHA and EPA greater than 3.0 g/person/day. In addition, the NOAEL value of 5,000 mg/kg bw/day found in a subchronic toxicity study in rats (details are found in Part 6.B.3) further supports the safe intake of DHA at the maximum exposure level of 1.5 g/day.

For Infant Formula Application

It is assumed that infants consume about 100 to 120 kcal/kg body weight (bw)/day, of which fat constitutes approximately 50% of calories, or approximately 5.5 to 6.7 g fat/kg bw/day (1 g of fat is equivalent to 9 kcal). Assuming incorporation of the proposed DHA ingredient at a maximum use level of 0.5% of total fatty acids (i.e., a maximum of 0.5% total fat as DHA), DHA-rich oil may be used at a maximum use level of 1.39% of dietary total fat since it has >36% DHA. The intended use will result in 27 to 33 mg DHA/kg bw/day. This DHA intake estimate 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).

Fuxing's DHA-rich oil is intended for use in infant formula in an identical manner as the currently approved oils. Fuxing's DHA-rich oil will replace, rather than add to, intake from these oils. Thus, cumulative EDIs are not expected to be changed.

3.C. 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 Consumption Data

For select conventional 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 less than 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/kg bw/day of DHA which is consistent with current DHA recommendations for term and preterm infants of 18 - 60 mg DHA/kg bw depending on the gestational age.

PART 4. SELF-LIMITING USE LEVELS

The use of DHA-rich oil will be based on the maximum use levels of menhaden oil in specific food categories established by FDA for menhaden oils such that the intake does not exceed 3.0 g/person/day. The use limitations of EPA and DHA were based on the content of EPA and DHA in menhaden oil, which is approximately 20%. Therefore, since DHA-rich oil contains a DHA content of ≥36% and no significant EPA level, it can reasonably be concluded that approximately 27.775% as much menhaden oil as DHA-rich oil will have to be consumed for the same intake of DHA. Inversely, any limitation of use levels from DHA-rich oil will have to be less than 50% of the use levels of menhaden oil to ascertain compliance with the safe intake level.

For infant formulas, no known self-limiting levels of use are associated with the DHA-rich oil. However, the ratio of ARA:DHA is expected to be in the range of 2:1 to 1:1.

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. As described above, DHA is a naturally occurring food component. It is reasonable to conclude that it was present in food prior to 1958.

PART 6. BASIS FOR GRAS DETERMINATION

6.A. Current Regulatory Status

Due to the compositional similarity and DHA content of fish and marine algal-derived oils to Fuxing's DHA-rich oil from *Schizochytrium* sp, the available scientific literature on the safety of these oils supports the safety of DHA-rich oil derived from *Schizochytrium* sp.

In 1989, the FDA affirmed the GRAS status of partially hydrogenated menhaden oil (with an iodine number 185) and fully hydrogenated menhaden oil for use in foods with certain limitations (U.S. FDA, 1989). Subsequently, in 1997, the FDA affirmed the GRAS status of menhaden oil and partially hydrogenated menhaden oil (with an iodine number S110), provided that under the conditions of intended use in foods, the total EPA + DHA daily intake does not exceed 3 g/person/day (U.S. 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 (U.S. FDA, 2005). Thus, in 21 CFR 184.1472(a)(3), menhaden oil is considered GRAS at a level providing no more than 3 g of combined DHA and EPA per person per day. Subsequently, GRAS notices on fish oils as sources of DHA and EPA (GRN 105 - FDA, 2002a; GRN 109 - FDA, 2002b; GRN 138 - FDA, 2004b; GRN 193 - FDA, 2006b; GRN 242 - FDA, 2008; GRN 371 - FDA, 2011a) have received no questions by the FDA. In addition, algal DHA derived from *Schizochytrium* sp. (GRN 137 - FDA, 2004a; GRN 732 - FDA, 2018b) received GRAS notice status with U.S. FDA to result in a maximum dietary exposure of less than 1.5 g of DHA per day (Table 18). Subsequently, algal DHA from *Ulkenia* sp. (GRN 319 - FDA, 2010) also has established a GRAS notice status with U.S. FDA for general food applications.

As shown in Table 18, algal DHA-rich oil derived from *Schizochytrium* sp. (GRN 553 - FDA, 2015; GRN 677 - FDA, 2017; GRN 731 - FDA, 2018a, and GRNs 776/777 - FDA, 2018c, 2018d) received GRAS notice status with U.S. FDA for infant formula applications. Other sources of DHA-rich oils include *Crypthecodinium cohnii* (GRN 41 - FDA, 2001) and tuna oils (GRN 94 - FDA, 2006a; GRN 379 - FDA, 2011b).

Table 18. Regulatory Approvals for Use of Algal DHA-Rich Oil 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 (>35%) derived from *Schizochytrium* sp.
GRN 319	2010	Algal DHA derived from *Ulkenia sp.*
GRN 732	2018	Algal oil (>45% DHA) derived from *Schizochytrium* sp. (except fish products)
Current notice		Algal oil (>36% DHA) derived from *Schizochytrium* sp. (except fish products)
Infant Formula		
GRN 41	2001	DHASCO (DHA-rich single-cell oil from *Crypthecodinium cohnii* for use in infant formula)

GRN 553	2015	Algal oil (40% DHA) derived from *Schizochytrium* sp.
GRN 677	2017	Algal oil (35-42% 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.
Current notice		Algal oil (≥36% 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 12), it is recognized that the information and data in those GRAS notices are pertinent to the safety 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.

Therefore, this notice incorporates by reference the safety and metabolism studies discussed in the previous GRAS notices (GRNs 137, 553, 677, 731/732, and 776/777) and will not discuss previously reviewed references in detail. Additionally, this notice discusses animal studies that have been published between July 2017 and March 2019 (i.e., since the FDA's review of DHA-rich oil for food applications in 2017-2018). The subject of the present GRAS notice is DHA-rich oil derived from *Schizochytrium* sp.

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 (TG), 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-contained 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 essential fatty acids availability.

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

Due to the abundance of papers, this mutagenicity and genotoxicity review limits the studies on DHA derived only from *Schizochytrium* sp., instead of covering DHA from various sources. The results of all mutagenicity and genotoxicity tests were negative.

A Recent Study

Bacterial reverse mutation assays for DHA-rich oil (Gao, 2019a)

In the reverse mutation assay using five strains of *Salmonella typhimurium* (TA97, TA98, TA100, TA102, and TA1535), 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 Fuxing's DHA-rich oil was non-mutagenic under the test conditions. Details Are described in Appendix C.

Studies Reviewed in Previous GRAS Notices

In GRNs 553 (pages 32-33, stamped pages 38-39), 677 (pages 33-41), and 731/732 (pages 28-30/pages 31-32), 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 et al., 2011a; 2011b; Lewis et al., 2016; Schmitt et al., 2012a), chromosome aberration assays (Fedorova 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 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 DHA Derived from *Schizochytrium* sp.

The results of various animal toxicity studies are summarized in Table 19. Due to the abundance of papers reporting no adverse effects of DHA in animals, this animal toxicity review has focused on studies of DHA derived from *Schizochytrium* sp., instead of DHA from various sources.

Acute Toxicity Study of Fuxing's DHA-rich Oil

Gao (2019b) evaluated the acute toxicity of DHA after oral administration in rats. The test substance was administered to young rats by oral gavage at doses of 0 (control), 1.0, 2.0, or 4.0 mL/kg body weight (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 groups. No treatment-related abnormalities were observed in the macroscopic examinations. In summary, an acute oral LD_{50} for DHA was determined to be above 4.0 mL/kg bw (the maximum dose volume) in both male and female rats. Details Are described in Appendix D.

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

In GRNs 553 (page 33, stamped page 39), 677 (pages 33-41), and 731-732 (pages 30-34; pages 33-37), the NOAELs of DHA-rich oils, DHA-ethyl ester, and DHA-rich microalgae were summarized as follows:

1) For DHA-rich algal oils, the NOAELs, established from subchronic toxicity studies, ranged from 3,258 to 5,000 mg/kg bw/day in rats (Fedorova-Dahms et al., 2011a; Hammond et al., 2001a; 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) For DHA-rich algal oil, the NOAELs, found from subchronic and/or reproductive toxicity studies of first and second generations, ranged from 2,069 to 7,464 mg/kg bw/day in rats (Fedorova-Dahms et al., 2011b; Schmitt et al., 2012b)

3) From developmental toxicity studies, the NOAELs were in the range of 2,000 to 5,000 mg/kg bw/day in rats (Falk et al., 2017; Schmitt et al., 2012b) and 1,800 mg/kg bw/day in NZW rabbits (Hammond et al., 2001b),

4) For DHA ethyl ester, the NOAEL was established at 2,000 mg/kg bw/day from a 9-month safety study in beagle dogs (Dahm et al., 2016), and

5) For DHA-rich microalgae (DRM), the NOAELs were estimated to be 1,368 mg DRM/kg bw/day (corresponding to approximately 305 mg DHA/kg bw/day) from a subchronic toxicity study in pigs (Abril et al., 2003), 22,000 mg/kg bw/day from a developmental toxicity study in rats (Hammond et al., 2001b), and 17,847 to 21,000 mg DRM/kg bw/day (corresponding to 1,500-1,800 mg DHA/kg bw/d) from a single generation reproduction study in rats (Hammond et al., 2001c).

Individual studies are summarized in Table 19.

Conclusion: For purposes of the safety evaluation, a NOAEL of 5,000 mg/kg bw/day was chosen for DHA-rich oil (or 2,000 mg/kg bw/day for DHA) in rats.

Table 19. Animal Toxicity Studies of DHA-Rich Oil or DHA-Rich Microalgae from *Schizochytrium sp.* Source

Material Studied	Study Design	Dose	Duration	Species	Primary Observations	NOAEL mg/kg bw/d unless noted otherwise	Reference
Acute Toxicity Study of Fuxing's DHA-rich Oil							
DHA-rich oil	Acute oral toxicity (gavage)	Up to 4 mL/kg bw	Single dose	Rat	Clinical signs of abnormality	LD_{50}>>>4 mL/kg bw	Gao et al., 2019
Studies Reviewed in Previous GRAS Notices							
DHA-rich oil	Acute oral toxicity (gavage)	5,000 mg/kg	14 d	Rat	No treatment-related adverse effects	LD_{50}>5 g/kg	Schmitt et al., 2012a
	Acute oral toxicity (diet)	1, 2.5, or 5% in diet	14 d	Rat	No treatment-related adverse effects	M, 3,258; F, 3,542 mg/kg bw	Schmitt et al., 2012a
	Subchronic toxicity (oral gavage)	1,000, 2,500, or 5,000 mg/kg bw/d	90 d	Rat	No treatment-related adverse effects	5,000	Lewis et al., 2016
	Subchronic toxicity (diet)	0.5, 1.5, or 5% in diet	90 d	Rat	Reduced food consumption in all treatment and fish oil control groups; attributed to high fat content rather than treatment.	3,246	Fedorova-Dahms et al., 2011a
	Subchronic toxicity (diet)	1, 2.5, or 5% in diet	90 d	Rat	No treatment-related adverse effects	M, 3,305; F, 3,679	Schmitt et al., 2012a
	Subchronic toxicity (diet)	400, 1,500, or 4,000 mg/kg bw/d	13 wk	Rat	No treatment-related adverse effects	4,000	Hammond et al., 2001a
	Subchronic and reproductive toxicity of first	1, 2.5, or 5% in diet	75-90 d	Rat	No treatment-related adverse effects	M during premating, 3,421; M after mating, 2,339; F during mating, 3,558; F	Schmitt et al., 2012b

	generation (diet)					during gestation, 3,117; F during lactation, 7,464	
	Subchronic toxicity of F1 (diet)	0.5, 1.5, or 5% in diet	90 d	Rat	No treatment-related adverse effects	4,260	Fedorova-Dahms et al., 2011b
	Developmental toxicity of mothers (diet)	0.5, 1.5, or 5% in diet	15 d	Rat	No treatment-related adverse effects	4,260	Fedorova-Dahms et al., 2011b
	Developmental and subchronic toxicity of second generation (diet)	1, 2.5, or 5% in diet	106-111 d	Rat	No treatment-related adverse effects in the 5% group males; Higher food consumption and BW in the 5% group females	M, 3,526; F, 2,069	Schmitt et al., 2012b
	Developmental toxicity (oral gavage)	1,000, 2,500, or 5,000 mg/kg bw/d	Gestat-ion days 6 to 20	Rat	No treatment-related adverse effects	5,000	Falk et al., 2017
	Developmental toxicity (gavage)	400-2,000 mg/kg bw/d	20 d	Rat	No treatment-related adverse effects	2,000	Schmitt et al., 2012b
	Developmental toxicity (gavage)	180, 600, or 1,800 mg/kg/d	30 d	Rabbit	High-dose (1,800) DHA oil and fish oil groups: F0-reduced food consumption and body wt	Maternal, 600; Develop: 1,800	Hammond et al., 2001b
DHA ethyl ester	Chronic toxicity (oral gavage)	150, 1,000, and 2,000 mg/kg bw/d	9 mo	Beagle dog	No treatment-related adverse effects	2,000	Dahm et al., 2016
DHA-rich micro-	Subchronic toxicity (diet)	1.17, 3.39, or 5.75 kg DRM per pig over 42 d; 2.68 kg	42-120 d	Pig	No treatment-related adverse effects (598, 261, 756, and 1,281 g DHA per pig during expt. period)	DRM, 1,368; DHA, ~305	Abril et al., 2003

algae (DRM)		DRM over 120 d					
	Developmental safety (diet)	0.6, 6.0, or 30% DRM in diet	15 d	Rat	No treatment-related adverse effects	22,000	Hammond et al., 2001b
	Single-generation reproduction toxicity (Diet)	0.6, 6.0, or 30% DRM in diet	13 wk	Rat	No treatment-related adverse effects	DRM - M, 17,847; F, 21,000; DHA - M, 1,500; F, 1,800	Hammond et al., 2001c

M=males; F=females.

6.B.4. Human Clinical Studies of DHA

Numerous algal and marine sources of DHA have been evaluated by the FDA and other global regulatory agencies over the past 18 years for 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. 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 (U.S. FDA, 2005). Since DHA represents approximately one half of combined DHA plus EPA, it is reasonable to consider that the acceptable daily intake (ADI) of DHA is 1.5 g/person/day.

Numerous GRAS notices have considered that DHA from marine algal oil is equivalent to that of fish oil. In addition, the bioequivalence of two types of algal DHA-rich oils (derived from either *Crypthecodinium cochnii* or *Schizochytrium* sp.) was demonstrated in preweaning farm piglets when administered in a blend with ARA oil (Fedorova-Dahms et al., 2014). Both algal DHA-rich oils were added to the formula at concentrations of 0.32% and 0.96% DHA (% of total fatty acids). There were no test article-related effects of any diet on piglet growth and development (clinical observations, body weight, and food consumption), clinical pathology parameters (hematology, clinical chemistry, coagulation, and urinalysis), and terminal necropsy parameters (macro- and microscopic pathology evaluations). DHA content in plasma, red blood cell (RBC), heart, liver, and brain showed dose related accumulation and confirmed no differences between the two algal DHA-rich oils. The authors concluded that dietary exposure to two types of algal DHA-rich oils was well tolerated by the preweaning piglets during the 3-week dosing period right after birth, and both algal DHA-rich oils (derived *Crypthecodinium cochnii* or *Schizochytrium* sp.) were bioequivalent.

We have evaluated recent scientific literature published between August 2017 and March 2019 to determine if there is any new information pertaining to the FDA's safety concerns that would contradict what was concluded and recommended by FDA in the 2005 final rule on menhaden oil and in the previous GRAS notices involving algal DHA-rich oils. We have limited the discussion to algal DHA-rich oil and unknown sources of DHA, and excluded the studies of DHA from marine sources and DHA ethyl ester. All of the studies of algal DHA-rich oil and unspecified sources of DHA reported no adverse events/effects on measured outcomes (Tables 19 to 21).

<u>Studies of DHA in Adults (Table 20)</u>

Daily doses of up to 2 g DHA from algal sources were not associated with treatment-related adverse effects on measured outcomes (Molfino et al., 2017; Smith et al., 2017; Manes et al., 2017; McDonald and Sieving, 2018). These studies measured effects of DHA on the ability of DHA incorporation in red blood cell (RBC) membranes; the potential differences in DHA incorporation ability in women with BRCA 1/2 gene mutation, women with family history of breast cancer, women with sporadic breast cancer, and healthy women (Molfino et al., 2017);

additional adjunctive benefits in patients with mild- to -moderate depression taking antidepressant medication in patients with mild to moderate major depressive disorder who were non-responsive to medication or psychotherapy (Smith et al., 2018); the safety, clinical symptoms, and changes of brain functional imaging in Spinocerebellar ataxia 38 (SCA38) patients (Manes et al., 2017); and electroretinography and visual test outcomes (McDonald and Sieving, 2018). Tolerance of the DHA was good, with only one case of rash and digestive discomfort, potentially related to DHA after 8 weeks of administration (Smith et al., 2018). In a study by McDonald and Sieving (2018), there were eight adverse events reported by four participants. All eight events were considered not related to DHA supplementation. In a study by Maines et al. (2017), no side effects or adverse events were reported during the 56-week DHA supplementation period.

In addition, daily doses up to 2.7 g DHA (unknown sources of DHA) also did not result in adverse effects on measured outcomes (Allaire et al., 2018; Cianci et al., 2017). Outcomes measured in these studies included phenotypic change in LDL-C and mechanisms responsible for the differential LDL-C response to DHA or EPA supplementation in subjects at risk of cardiovascular disease (Allaire et al., 2018), and menopausal symptoms, sexuality and quality of life, and on the auditory brainstem response in perimenopausal women (Cianci et al., 2017).

Studies in Children (Table 21)

In a study by Devlin et al. (2017), toddlers aged 13.4 months were randomized to receive DHA (200 mg/d; 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.

Demmelmair et al. (2018) also reported that supplementation of algal DHA doses from 0 to 7 mg/kg (manufacturer-Nutricia; algal type not specified) for 6 months had no adverse effects on neurological and intellectual functions in children with phenylketonuria.

Studies of DHA in Pregnant Women and Offspring (Table 22)

Foster et al. (2017) determined if DHA given during pregnancy to obese mothers resulted in lower offspring adiposity. Mothers with gestational diabetes or obesity were randomized to receive DHA supplementation at 800 mg/day (manufacturer-DSM; DHASCO -algal type not specified) or placebo (corn/soy oil) starting at 25–29 weeks of gestation. Anthropometric measures were collected at birth, and maternal erythrocyte DHA and arachidonic acid levels were measured at the 26- and 36-week gestation. At the two- and four-year follow-up time points, offspring adiposity measures along with a diet recall were assessed. No adverse effects of DHA were reported.

Mulder et al. (2018) also reported that children (5–6 years) whose mothers received 400 mg/day DHA (unspecified source of DHA) or a placebo during pregnancy resulted in no adverse effects on infant development persist into early childhood.

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 Infant Formula Supplemented with 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. The studies reviewed in these notifications supported the safe use of DHA in infant formula up to 0.96% of total fatty acids.

It is believed that DHA-rich oil derived from *Schizochytrium* sp. is bioequivalent to DHA from another type of algal oil (such as *C. cohnii*) or fish oil. Thus, we have focused on the studies of infant formulas supplemented with DHA from algal sources (*Schizochytrium* sp., *C. cohnii*, and unspecified sources) to make general conclusions about the safety of algal DHA-rich oil derived from *Schizochytrium* sp. Our review focused on papers published between July 2017 and March 2019.

Studies of Term Infants

In the DHA Intake and Measurement of Neural Development (DIAMOND) studies of Colombo et al. (2017), healthy, term infants were enrolled at 1-9 day 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), 0.32, 0.64, or 0.96% algal DHA derived from *C. cohnii*. All 3 DHA-supplemented formulas also provided 0.64% ARA derived from *M. alpina* (Table 23). Algal DHA, up to 0.96% of total FAs, was well tolerated, and no adverse effects were noted on measured outcomes including tolerance, adverse events, growth, RBC concentrations of fatty acids, visual acuity, cognitive function, and school readiness.

A previous GRAS notice reviewed the study by Chase et al. (2015), which investigated the effect of supplementation of DHASCO-5 oil derived from *Schizochytrium* sp. on stimulated inflammatory cytokine production in white blood cells (WBC) in infants with a high genetic risk for type 1 diabetes. DHA-rich oil supplementation began either in the last trimester of pregnancy (41 infants) or in the first 5 months after birth (57 infants) with a follow-up at up to 36 months of age. This study showed that supplementation of infant diets with DHA-rich oil was safe. No adverse effects were noted on measured outcomes such as concentrations of DHA in infant and maternal RBC membranes and in breast milk, and inflammatory cytokines.

Preterm Infants

Since August 2017, no new infant studies with DHA derived from *Schizochytrium* sp. were published. Previous GRAS notices reviewed the studies by Almaas et al. (2015; 2016), which 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 improve behavioral and cognitive outcomes at 8 years of age. In these studies, human milk supplemented with 32 mg DHA (0.86% of total fatty acids) and 31 mg ARA (0.91% of total fatty acids) was fed to preterm infants for 9 weeks after birth with an 8-year follow-up. No adverse effects were reported on behavioral or cognitive outcomes.

Table 20. Adult Human Studies of DHA*

Objective	Subject	Daily Dose	Duration; Design	Measurements	Reference
Studies of DHA from Microalgae Sources					
To assess the ability of DHA incorporation in RBC membranes, in breast cancer patients and in healthy controls and the potential differences in the DHA incorporation ability	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-DMF, Italy; 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, DHA, and Omega-3 Index	Molfino et al., 2017
To test if DHA dietary supplementation improves macular function in patients with a macular disorder, namely Stargardt disease associated with mutations in the ABCA4 gene	11 subjects (2 males, 9 females) with Stargardt disease; 26-63 y (median 40 y)	0 or 2 g/d DHA (manufacturer-Martek/DSM; algae type, NA; 40% DHA)	3 mo; X	Food frequency and NEI-VF25 questionnaires; complete ophthalmic exam; multifocal electroretinography (ERG, primary outcome) and 30-Hz flicker ERG; Humphrey 10-2 visual field; D15 color tests; serum lipids; adverse events	McDonald 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 of DHA	Smith et al., 2018
To evaluate effects of DHA on the safety, its	10 Spinocerebellar ataxia 38 (SCA38)	Phase 1- 0 or 600 mg DHA/d;	A total of 56 wk-16	Standardized clinical assessment; brain 18-	Manes et al., 2017

efficacy for clinical symptoms, and changes of brain functional imaging	patients; mean age 48.7 y	Phase 2- 600 mg DHA/d only (manufacturer-Sofedus; algae type, NA)	wk-double blind, followed by 40 wk open-label trial	fluorodeoxyglucose positron emission tomography; Electroneurography; ELOVL5 expression; side effects	
Source, Not specified					
To examine the phenotypic change in LDL and mechanisms responsible for the differential LDL-C response to DHA or EPA supplementation	48 men and 106 women at risk of cardiovascular disease; 18-70 y	3 phases: 2.7 g DHA, 2.7 g EPA, and 3.0 g corn oil (Source, NA)	10 wk; X	Anthropometric measures, compliance; serum LDL particle sizes and serum concentrations of proprotein convertase subtilisin/kexin type 9 (PCSK9), glucose, total apoB100, apoCIII, and insulin	Allaire et al., 2018
To evaluate the effect of DHA 625 mg in women who experience menopausal symptoms, on sexuality and quality of life, and on the auditory brainstem response	56 perimenopausal women; age 49-53 y	625 mg DHA; no placebo control (Source, NA); no placebo control	6 mo; single arm	Perimenopausal symptoms measured by Kupperman Index; female Sexual Function Index (FSFI), and the Female Sexual Distress Scale (FSDS)	Cianci et al., 2017

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

Table 21. Human Studies of DHA in Toddlers and Children*

Objective	Subject	Dose	Duration; Design	Measurements	Reference
Studies of Algal DHA					
To investigate the effects of DHA and ARA on cognitive development in toddlers	133 healthy term (37–41 weeks gestation) toddlers, mean age 1.34 y	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; P	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
To study whether a DHA supply modified plasma DHA and neurological and intellectual functioning in phenylketonuria	109 children with phenylketonuria, age 5 to 13 y	5 DHA doses from 0 to 7 mg/kg (0, 20, 43, 80, and 127 mg DHA/d) from algal source (manufacturer-Nutricia; type of algae-NA)	6 mo; P	Neurological and intellectual functions; non-fasted blood (serum) concentrations of lipids and phenylalanine; plasma glycerophospholipid (GPL) fatty acids	Demmel-mair et al., 2018

*Excluding studies of DHA from fish oil source or DHA-ethyl ether; ARA=arachidonic acid; DHA=docosahexaenoic acid; mo=months; NA=not available; P=parallel design.

Table 22. Human Studies of DHA during Pregnancy*

Objective	Subject	Dose	Duration	Measurements	Reference
Studies of DHA from Algal Sources					
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
Studies of DHA from Unknown Sources					
To determine whether the observed effects of fetal DHA inadequacy on infant development persist into early childhood	Pregnant women at 16 weeks of gestation-age, NA; 200 infants (96 maternal DHA; 104 placebo)	400 mg/d DHA or a placebo during pregnancy	20 wk from 16 wk of gestation until delivery; Follow-up of children at 5.75 y; P	The association of maternal DHA intake and status in gestation with child neurodevelopment test scores; associations of child dietary DHA with maternal dietary and erythrocyte markers of DHA sufficiency during gestation	Mulder et al., 2018

*Excluding studies of DHA from fish oil source or DHA-ethyl ether; ARA=arachidonic acid; DHA=docosahexaenoic acid; NA=not available; P=parallel design; y=years.

Table 23. Human Studies of DHA in Term-Infants*

Objective	Subject	Dose	Duration	Measurements	Reference
Study of DHA from Algal Source					
To investigate the DHA/ARA balance as an important variable in the contribution of LCPUFAs to cognitive and behavioral development in infancy	343 term infants, 2,490 and 4,200 g at birth	3 concentrations of DHA (Mead Johnson; derived from *C. cohnii*): 0.32%, 0.64%, or 0.96% (or 0, 17, 34, or 51 mg DHA/100 kcal) with 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	Columbo et al., 2017

*Excluding studies of DHA from fish oil source or DHA-ethyl ether; ARA=arachidonic acid; IQ=intelligence quotient; LCPUFAs= long chain polyunsaturated fatty acids; mo=months; y=years.

6.B.5. Potential Adverse Effects

As discussed in Section 6.B.4, 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). In affirming the GRAS status of menhaden oil, FDA concluded that the use of menhaden oil as a direct food ingredient is GRAS, provided that the combined daily intake of EPA and DHA from consumption of menhaden oil does not exceed 3 g/person/day. To assure that the combined exposure to EPA and DHA would not exceed 3 g/person/day, FDA established maximum levels of use of 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). It is noteworthy that the Institute of Medicine (IOM, 2002) has not established any Tolerable Upper Intake Levels (UL) for DHA and EPA while establishing Dietary Reference Intakes for Americans.

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 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. Fuxing's manufacturing process for DHA-rich oil meets the cGMP requirements and uses common food industry materials and processes. Fuxing observes the principles of HACCP-controlled manufacturing process and rigorously tests its final production batches to verify adherence to quality control specifications.

2. 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 PCBs, PAHs, pesticide residues, solvent residues, domoic acid, and mycotoxins have been detected from Fuxing's DHA-rich oil.

3. As the DHA-rich oil in this GRAS notice has similar specifications and composition to those described in previous FDA GRAS notices (GRNs 137, 553, 677, 731/732, and 776), it is concluded that Fuxing's DHA-rich oil is substantially equivalent to those described in GRNs 137, 553, 677, 731/732, and 776. Thus, it is recognized that the information and data presented or reviewed in the GRN notices are pertinent to

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. (GRNs 137, 553, 677, 731-732, and 776).

4. 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 27.775% 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.

5. Fuxing's DHA-rich oil may be used at a maximum use level of 0.5% of total fat as DHA (U.S. FDA, 2001) in infant formulas for term and preterm infants. This level corresponds to a maximum of 1.39% of dietary fat as Fuxing's DHA-rich oil (U.S. FDA, 2001). The intended use level is the same as another approved use 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 nutritional food ingredient for infants.

6. It is assumed that 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.

7. In the 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 5,000 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 have been evaluated by the FDA and other global regulatory agencies over the past 18 years for the proposed incorporation of DHA in foods for human consumption. Relevant U.S. GRAS notifications include GRNs 137, 553, 677, 731/732, and 776/777 (FDA, 2004a; 2015; 2017; 2018a-d). 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 fish and algae-derived oils to Fuxing's DHA-rich oil, the available scientific literature on the safety of these oils supports the safety of 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 of the proposed GRAS substance, 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 the health benefits 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. The literature indicates that DHA-rich oil offers consumers health benefits without serious adverse effects.

Fuxing observes the principles of HACCP-controlled manufacturing process and rigorously tests its final production batches to verify adherence to quality control specifications.

The information and data provided by 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 when prepared according to cGMP.

It is concluded that 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.

Allaire J, Vors C, Tremblay AJ, Marin J, Charest A, Tchernof A, Couture P, Lamarche B. High-dose DHA has more profound effects on LDL-related features than high-dose EPA: The ComparED study. J Clin Endocrinol Metab. 2018;103:2909-17.

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.

Chase HP, Boulware D, Rodriguez H, Donaldson D, Chritton S, Rafkin-Mervis L, Krischer J, Skyler JS, Clare-Salzler M; Type 1 Diabetes TrialNet Nutritional Intervention to Prevent (NIP) Type 1 Diabetes Study Group. Effect of docosahexaenoic acid supplementation on inflammatory cytokine levels in infants at high genetic risk for type 1 diabetes. Pediatr Diabetes. 2015;16:271-9.

Cianci A, Maiolino L, Giunta G, Rapisarda AMC, Di Mauro P, Caruso S. Neurovegetative disorders of perimenopausal women treated with docosahexaenoic acid (DHA, 625 mg). Gynecol Endocrinol. 2017;33:980-4.

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.

Dahms I, Beilstein P, Bonnette K, Salem N Jr. Safety of docosahexaenoic acid (DHA) administered as DHA ethyl ester in a 9-month toxicity study in dogs. Food Chem Toxicol. 2016;92:50-7.

Demmelmair H, MacDonald A, Kotzaeridou U, Burgard P, Gonzalez-Lamuno D, Verduci E, Ersoy M, Gokcay G, Alyanak B, Reischl E, Müller-Felber W, Faber FL, Handel U, Paci S, Koletzko B. Determinants of plasma docosahexaenoic acid levels and their relationship to neurological and cognitive functions in PKU patients: A double blind randomized supplementation study. Nutrients. 2018;10.

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).

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 and Drug Administration (FDA). 1989. Substances Affirmed as Generally Recognized as Safe: Hydrogenated and partially hydrogenated menhaden oils (Final rule) (21 CFR, Part 184, Docket No. 866-0289). Fed Reg (U.S.) 54 (178):38219.

FDA**.** 1997. Substances affirmed as Generally Recognized as Safe: Menhaden oil; Final rule. Federal Reg. 62:30751.

FDA. 2001. Agency Response Letter. GRAS Notice No. GRN000041. DHASCO (docosahexaenoic acid-rich single-cell oil) and ARASCO (arachidonic acid-rich single-cell oil). May 17, 2001. http://www.fda.gov/Food/FoodIngredientsPackaaina/GenerallyRecognizedasSafeGRAS/GRASListingducm 154 126.htm.

FDA. 2002a. Agency Response Letter. GRAS Notice No. GRN000105. Fish oil concentrate. October 12, 2002. http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm153913.htm.

FDA. 2002b. Agency Response Letter. GRAS Notice No. GRN 109 Tuna oil. Dec 4, 2002. https://wayback.archive-it.org/7993/20171031032432/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm153918.htm

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

FDA. 2004b. Agency Response Letter. GRAS Notice No. GRN000138. Fish oil. April 20, 2004. http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm153965.htm.

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

FDA. 2006a. Agency Response Letter. GRAS Notice No. GRN000094. Docosahexaenoic acid-rich oil from tuna (DHA-rich tuna oil) and arachidonic acid-rich oil from *Mortierella alpina (AA-rich fungal oil).* April 18, 2006. http://www.fda.gov/Food/FoodIngredientsPackanina/GenerallyRecognizedasSafeGRAS/GRASListingducm 154630.htm.

FDA. 2006b. Agency Response Letter. GRAS Notice No. GRN000193. Fish oil (predominantly sardine and anchovy); tuna oil. August 3, 2006. http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm154669.htm.

FDA. 2008. Agency Response Letter. GRAS Notice No. GRN 000242. Krill oil. October 14, 2008. https://wayback.archive-it.org/7993/20171031031428/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm154374.htm

FDA. 2010. Agency Response Letter. GRAS Notice No. GRN000319. Micro-algal oil *Ulkenia* sp. SAM2179. August 4, 2010.

FDA. 2011a. Agency Response Letter. GRAS Notice No. GRN000371. Krill oil. July 22, 2011. https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm267323.htm.

FDA. 2011b. Agency Response Letter. GRAS Notice No. GRN000379. November 8, 2011. http://www.fda.gov/Food/FoodIngredientsPackanina/GenerallyRecognizedasSafeGRAS/GRASListingducm 282570.htm.

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.

Fedorova-Dahms I, Marone PA, Bailey-Hall E, Ryan AS. Safety evaluation of DHA-rich algal oil from *Schizochytrium* sp. Food Chem Toxicol. 2011;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. 2011;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, Kier LD, Mast RW, Sander WJ. Safety assessment of DHA-rich microalgae from *Schizochytrium* sp. Regul Toxicol Pharmacol. 2002;35:255-65.

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

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

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

Institute of Medicine (IOM). 2002. The Dietary Reference Intake for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids. The National Academies Press. Washington D.C.

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.

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.

Manes M, Alberici A, Di Gregorio E, Boccone L, Premi E, Mitro N, Pasolini MP, Pani C, Paghera B, Perani D, Orsi L, Costanzi C, Ferrero M, Zoppo A, Tempia F, Caruso D, Grassi M, Padovani A, Brusco A, Borroni B. Docosahexaenoic acid is a beneficial replacement treatment for spinocerebellar ataxia 38. Ann Neurol. 2017;82:615-21.

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(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.

Mulder KA, Elango R, Innis SM. Fetal DHA inadequacy and the impact on child neurodevelopment: a follow-up of a randomised trial of maternal DHA supplementation in pregnancy. Br J Nutr. 2018;119:271-9.

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.

7.B. Reference that Is Not Generally Available

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

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

Appendix A. Certificates of Analysis

Please see an attached pdf file.

Appendix B. Identification of Fuxing's DHF Strain. China Center for Type Culture Collection (CCTCC) Report No. 2019027. 2019

Please see an attached pdf file.

CNAS 中国认可 检测 TESTING CNAS L3788

Analytical Report

Sample Code	502-2019-00010198	Report date	19-Apr-2019
Certificate No.	AR-19-SU-017436-03		

*This analytical report replaces the previous issued analytical report no.: AR-19-SU-017436-01

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/ AR-19-SU-017436-03
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:	19-Apr-2019
Arrival Temperature (°C)	17.6
Sample Weight	500g*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	
^# SU055 Molybdenum (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
Molybdenum (Mo)	<0.03	mg/kg	0.03	
^# SU058 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)	41.4	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
# SU51A Pesticide Screening(GC) Method: BS EN 12393:2013				
Screened pesticides	<LOQ	mg/kg		

	Results	Unit	LOQ	LOD

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

	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				
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
☆ GFL01 Dioxins and Furans (17 PCDD/F) Method: Internal, GC-MS/MS				
2,3,7,8-TetraCDD	< 0.0309	pg/g		
1,2,3,7,8-PentaCDD	< 0.0407	pg/g		
1,2,3,4,7,8-HexaCDD	< 0.0619	pg/g		
1,2,3,6,7,8-HexaCDD	< 0.0847	pg/g		
1,2,3,7,8,9-HexaCDD	< 0.0798	pg/g		
1,2,3,4,6,7,8-HeptaCDD	< 0.130	pg/g		
OctaCDD	< 0.945	pg/g		
2,3,7,8-TetraCDF	< 0.0847	pg/g		
1,2,3,7,8-PentaCDF	< 0.0586	pg/g		
2,3,4,7,8-PentaCDF	< 0.0912	pg/g		
1,2,3,4,7,8-HexaCDF	< 0.0961	pg/g		
1,2,3,6,7,8-HexaCDF	< 0.0879	pg/g		
1,2,3,7,8,9-HexaCDF	< 0.0651	pg/g		
2,3,4,6,7,8-HexaCDF	< 0.0798	pg/g		
1,2,3,4,6,7,8-HeptaCDF	< 0.0912	pg/g		
1,2,3,4,7,8,9-HeptaCDF	< 0.0635	pg/g		
OctaCDF	< 0.195	pg/g		
WHO(2005)-PCDD/F TEQ (lower-bound)	Not Detected	pg/g		
WHO(2005)-PCDD/F TEQ (medium-bound)	0.0840	pg/g		
WHO(2005)-PCDD/F TEQ (upper-bound)	0.168	pg/g		
	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	

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

	Results	Unit	LOQ	LOD
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 208/2005 (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	
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	0.05	
Free fatty acids (as oleic acid)	0.26	%	0.01	
☆ 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	

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

	Results	Unit	LOQ	LOD
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	
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	

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

	Results	Unit	LOQ	LOD
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.				
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)	0.04	%	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	

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

	Results	Unit	LOQ	LOD
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	
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	%	0.05	
Sum of Omega 6 Isomers	18.21	%	0.05	
Total Fat as Triglycerides	91.43	%	0.1	
Total Fatty Acids Calc.	87.69	%	0.1	
Total Monounsaturated Fatty Acids	3.48	%	0.05	
Total Polyunsaturated Fatty Acids	58.06	%	0.05	
Total Saturated Fatty Acids	26.16	%	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 13.04-5 : 2013-08, mod.				
Linuron	<0.01	mg/kg	0.01	
Bromacil	<0.01	mg/kg	0.01	
Pyrethrins	<0.1	mg/kg	0.1	
☆ UM5Y6 Aerobic Plate Count /ml AOAC 990.12 Method: AOAC 990.12				
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 121501 Method: AOAC-RI 121501				

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

		Results	Unit	LOQ	LOD
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 (0.06)	(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 (0.06)	(a) Captan (0.06)	(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) 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) 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) Phenkaptori (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) Quintozene (0.01)	(a) Quizalofop-P-ethyl (0.01)	(a) Silafluofen (0.06)
(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) Tolclofos (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

Ally Dong	Claire Wang	Jack He
Authorized Signatory	Authorized Signatory	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

For and on behalf of Eurofins Technology Service (Suzhou) Co., Ltd

END OF REPORT

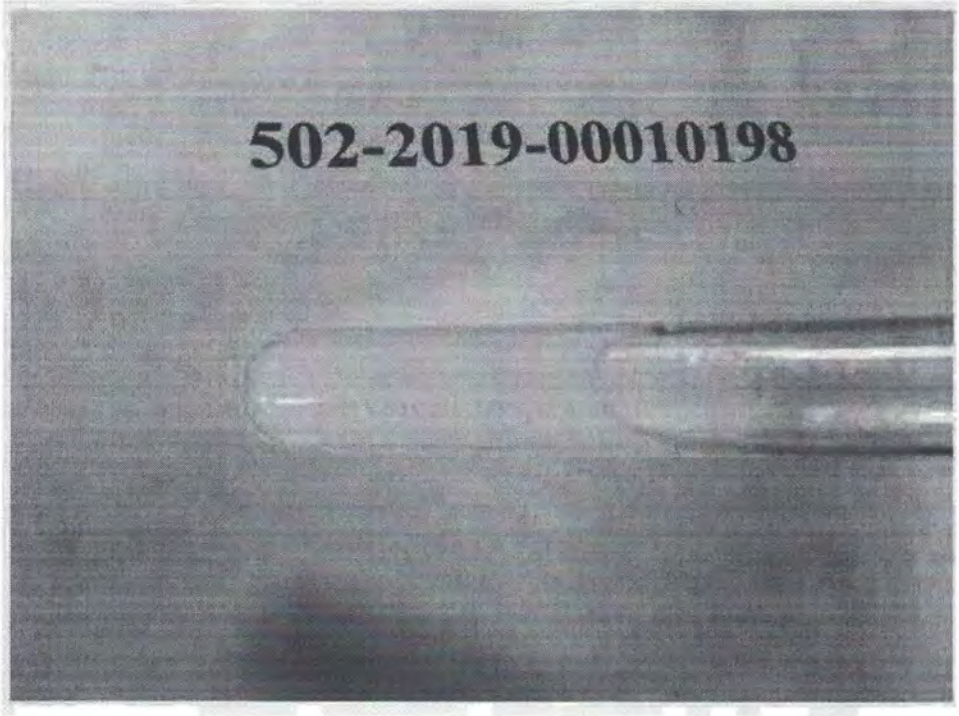
Eurofins Tech. Service (Suzhou) Co., Ltd
No. 101, Jialingjiang Road, SND
Suzhou 215000
Jiangsu Province, P.R. China

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

EUROFINS TECHNOLOGY SERVICE (SUZHOU) CO., LTD eurofins TESTING SERVICE

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

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	
SU055	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)	45.6	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

		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 208/2005 (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

		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 215000
Jiangsu Province, P.R. China

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

		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

	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 215000
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	%	0.05	
Sum of Omega 6 Isomers	7.52	%	0.05	
Total Fat as Triglycerides	92.31	%	0.1	
Total Fatty Acids Calc.	88.42	%	0.1	
Total Monounsaturated Fatty Acids	1.25	%	0.05	
Total Polyunsaturated Fatty Acids	46.96	%	0.05	
Total Saturated Fatty Acids	40.22	%	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 13.04-5 : 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 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 (0.06)	(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 (0.06)	(a) Captan (0.06)	(a) Captan/THPI (Sum calculated as Captan) ()	(a) Carbophenothion (0.05)	(a) Carbophenothion-methyl (0.05)	(a) Carboxin (0.06)
(a) Chlorbenside (0.06)	(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) Fenflutrirn (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) Flusilinate-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 (0.06)	(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 (0.06)

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

(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) 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

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

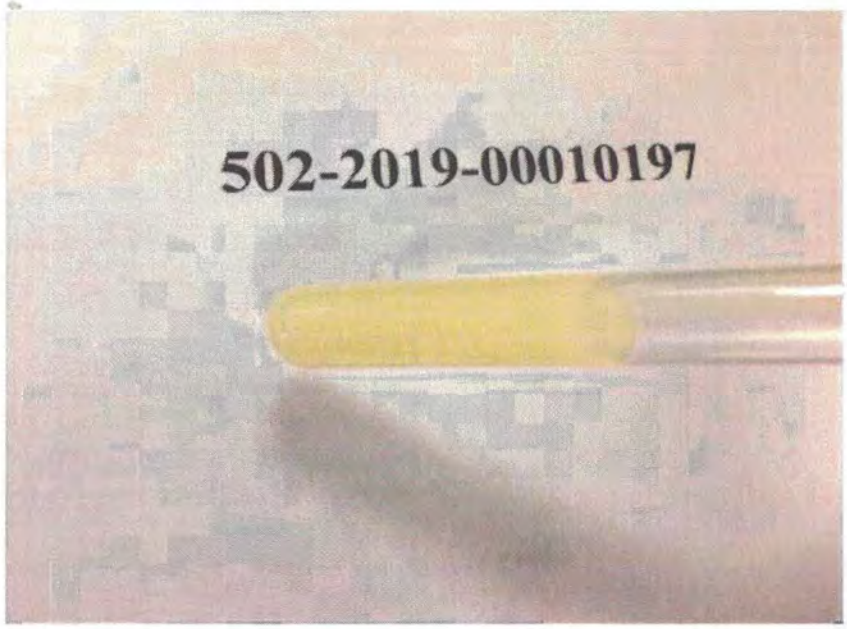
END OF REPORT

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

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

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

CNAS 中国认可 检测 TESTING CNA S L3788

Analytical Report

Sample Code	502-2019-00010195	Report date	21-Apr-2019
Certificate No.	AR-19-SU-017442-03		

*This analytical report replaces the previous issued analytical report no.: AR-19-SU-017442-01

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/ AR-19-SU-017442-03
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:	19-Apr-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	
△# SU055 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	
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

	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				
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
☆ GFL01 Dioxins and Furans (17 PCDD/F) Method: Internal, GC-MS/MS				
2,3,7,8-TetraCDD	< 0.0310	pg/g		
1,2,3,7,8-PentaCDD	< 0.0408	pg/g		
1,2,3,4,7,8-HexaCDD	< 0.0620	pg/g		
1,2,3,6,7,8-HexaCDD	< 0.0848	pg/g		
1,2,3,7,8,9-HexaCDD	< 0.0799	pg/g		
1,2,3,4,6,7,8-HeptaCDD	< 0.131	pg/g		
OctaCDD	< 0.946	pg/g		
2,3,7,8-TetraCDF	< 0.0848	pg/g		
1,2,3,7,8-PentaCDF	< 0.0587	pg/g		
2,3,4,7,8-PentaCDF	< 0.0914	pg/g		
1,2,3,4,7,8-HexaCDF	< 0.0962	pg/g		
1,2,3,6,7,8-HexaCDF	< 0.0881	pg/g		
1,2,3,7,8,9-HexaCDF	< 0.0653	pg/g		
2,3,4,6,7,8-HexaCDF	< 0.0799	pg/g		
1,2,3,4,6,7,8-HeptaCDF	< 0.0914	pg/g		
1,2,3,4,7,8,9-HeptaCDF	< 0.0636	pg/g		
OctaCDF	< 0.196	pg/g		
WHO(2005)-PCDD/F TEQ (lower-bound)	Not Detected	pg/g		
WHO(2005)-PCDD/F TEQ (medium-bound)	0.0841	pg/g		
WHO(2005)-PCDD/F TEQ (upper-bound)	0.168	pg/g		

	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	

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

	Results	Unit	LOQ	LOD
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 208/2005 (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	
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)	0.38	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	

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

		Results	Unit	LOQ	LOD
	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	
	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	

	Results	Unit	LOQ	LOD
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.				
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)	0.04	%	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	

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

	Results	Unit	LOQ	LOD
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	
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 13.04-5 : 2013-08, mod.				
Linuron	<0.01	mg/kg	0.01	
Bromacil	<0.01	mg/kg	0.01	
Pyrethrins	<0.1	mg/kg	0.1	
☆ UM5Y6 Aerobic Plate Count /ml AOAC 990.12 Method: AOAC 990.12				
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 121501 Method: AOAC-RI 121501				

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

	Results	Unit	LOQ	LOD
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) 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) 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) 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) Lindrin (0.02)
(a) Malaoxon (0.05)	(a) Malathion (0.02)	(a) Malathion (Sum) ()	(a) Mecarbam (0.04)	(a) Mepronil (0.01)	(a) Methiocarb (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 (0.06)	(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 (0.06)
(a) Sulfotep (0.01)	(a) Tebufenpyrad (0.01)	(a) Technazene (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

Ally Dong	Claire Wang	Jack He
Authorized Signatory	Authorized Signatory	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

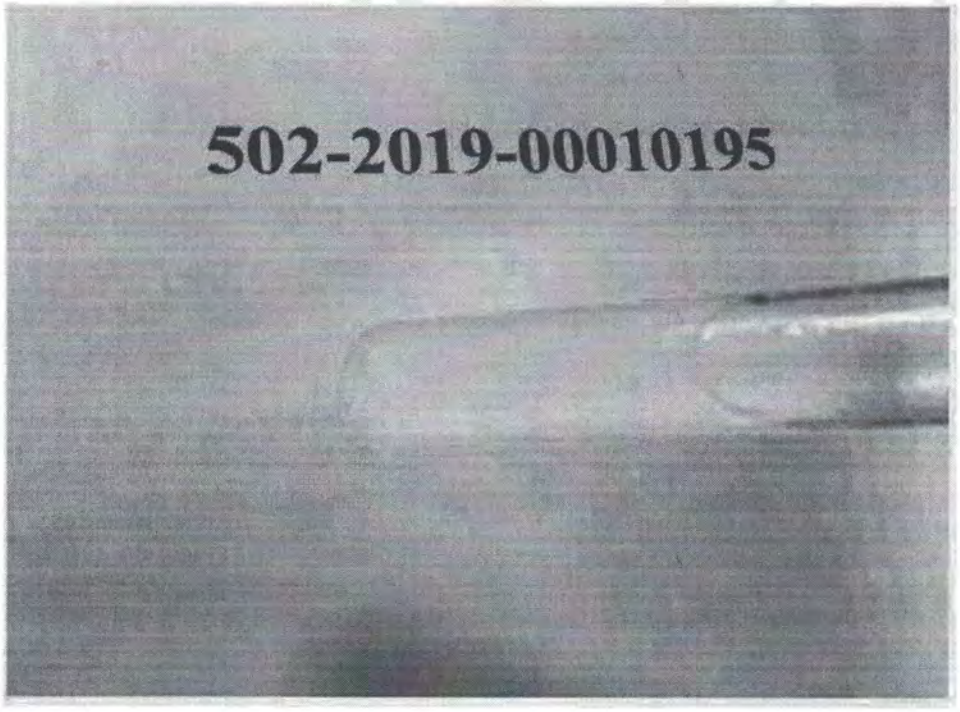
END OF REPORT

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

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

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

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	
SU051	Manganese (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Manganese (Mn)	**<0.1**	mg/kg	0.1	
SU055	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)	**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

		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 (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	0.6	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 215000
Jiangsu Province, P.R. China

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

		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	
☆ 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 215000
Jiangsu Province, P.R. China

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

	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

	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)	2.59	%	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 215000
Jiangsu Province, P.R. China

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

	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 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 0.491 mg/100 g.

List of screened molecules (* = limit of quantification)

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

(a) 2-Phenylphenol (0.01)	(a) Acetochlor (0.06)	(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 (0.06)	(a) Captan (0.06)	(a) Captan/THPI (Sum calculated as Captan) ()	(a) Carbophenothion (0.05)	(a) Carbophenothion-methyl (0.05)	(a) Carboxin (0.06)
(a) Chlorbenside (0.06)	(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) Dichlobanil (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) 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 (0.06)	(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 (0.06)	(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 (0.06)

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

(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) 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

Claire Wang
Authorized Signatory

Shine Xie
Authorized Signatory

EXPLANATORY NOTE

LOQ: Limit of Quantification
< LOQ: Below Limit of Quantification
N/A means Not applicable
Δ 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

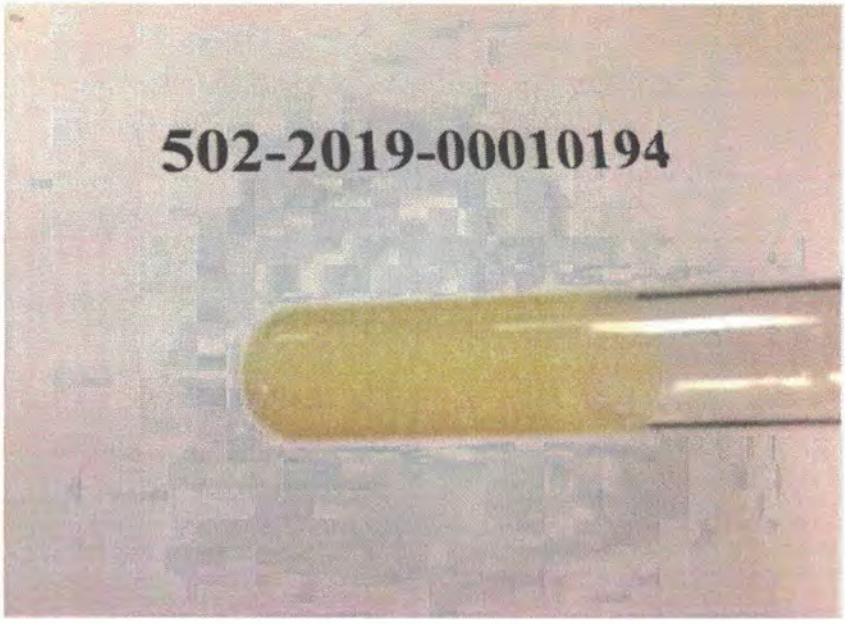
END OF REPORT

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

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

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	502-2019-00010196	Report date	19-Apr-2019
Certificate No.	AR-19-SU-017438-03		

*This analytical report replaces the previous issued analytical report no.: AR-19-SU-017438-01

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

Our reference:	502-2019-00010196/ AR-19-SU-017438-03
Client Sample Code:	D18122701J
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:	19-Apr-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	
△# SU055 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)	22.4	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

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 TECHNOLOGY SERVICE (SUZHOU) CO.,LTD eurofins TESTING SERVICE

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

	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				
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	4748	mg/kg	10	
	Results	Unit	LOQ	LOD
☆ GFL01 Dioxins and Furans (17 PCDD/F) Method: Internal, GC-MS/MS				
2,3,7,8-TetraCDD	< 0.0299	pg/g		
1,2,3,7,8-PentaCDD	< 0.0393	pg/g		
1,2,3,4,7,8-HexaCDD	< 0.0597	pg/g		
1,2,3,6,7,8-HexaCDD	< 0.0818	pg/g		
1,2,3,7,8,9-HexaCDD	< 0.0770	pg/g		
1,2,3,4,6,7,8-HeptaCDD	< 0.126	pg/g		
OctaCDD	< 0.912	pg/g		
2,3,7,8-TetraCDF	< 0.0818	pg/g		
1,2,3,7,8-PentaCDF	< 0.0566	pg/g		
2,3,4,7,8-PentaCDF	< 0.0881	pg/g		
1,2,3,4,7,8-HexaCDF	< 0.0928	pg/g		
1,2,3,6,7,8-HexaCDF	< 0.0849	pg/g		
1,2,3,7,8,9-HexaCDF	< 0.0629	pg/g		
2,3,4,6,7,8-HexaCDF	< 0.0770	pg/g		
1,2,3,4,6,7,8-HeptaCDF	< 0.0881	pg/g		
1,2,3,4,7,8,9-HeptaCDF	< 0.0613	pg/g		
OctaCDF	< 0.189	pg/g		
WHO(2005)-PCDD/F TEQ (lower-bound)	Not Detected	pg/g		
WHO(2005)-PCDD/F TEQ (medium-bound)	0.0811	pg/g		
WHO(2005)-PCDD/F TEQ (upper-bound)	0.162	pg/g		
	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	22	mg/100 g	1	
Cholesterol	356	mg/100 g	1	
Campesterol	9	mg/100 g	1	
Campestanol	5	mg/100 g	1	
Stigmasterol	40	mg/100 g	1	
Unidentified sterols	235	mg/100 g	1	
Sitosterol	66	mg/100 g	1	
Sitostanol+ delta-5-avenasterol	6	mg/100 g	1	
Delta-5,24-stigmastadienol	10	mg/100 g	1	
Delta-7-stigmastenol	31	mg/100 g	1	
delta-7-Avenasterol	5	mg/100 g	1	
Cycloartenol	2	mg/100 g	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

	Results	Unit	LOQ	LOD
24-Methylenecycloartanol	1	mg/100 g	1	
Citrostadienol	1	mg/100 g	1	
Total plant sterols + plant stanols	428	mg/100 g	1	
☆ JC00V PAH acc. to EU 208/2005 (15+1) Method: Internal, GC-MS				
5-Methylchrysene	<1	µg/kg	1	
Benz(a)anthracene	<0.5	µg/kg	0.5	
Benzo(a)pyrene	0.8	µg/kg	0.5	
Benzo(b)fluoranthene	<0.5	µg/kg	0.5	
Benzo-(c)-fluorene	1.6	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	0.7	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	3.1	µg/kg		
Sum PAH 4	1.5	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	
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)	0.60	mg KOH/g	0.05	
Free fatty acids (as oleic acid)	0.30	%	0.01	
☆ QA01L p-Anisidine Value Method: AOCS Cd 18-90				
p-Anisidine Value	20.3		1	
☆ QA02L Color (Lovibond Scale) Method: AOCS Cc 13e-92; ISO 15305				
Color, red scale, 1 inch cell path	2.2			
Color, yellow scale, 1 inch cell path	22			
☆ 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	

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

	Results	Unit	LOQ	LOD
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	
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	

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

	Results	Unit	LOQ	LOD
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	0.30	%	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)	45	mg/kg	1	
☆ QA967 Unsaponifiable Matter (Ethyl ether ext) Method: AOCS Ca 6b-53				
Unsaponifiable matter	1.95	%	0.05	
☆ QAA07 Vomitoxin (Deoxynivalenol, DON) LC-MSMS Method: Food Addit Contam Part A, 2013:30(3),541-9.				
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)	0.05	%	0.02	
C14:0 Tetradecanoic (Myristic)	0.43	%	0.02	
C14:1 Tetradecenoic (Myristoleic)	<0.02	%	0.02	
C15:0 Pentadecanoic	1.13	%	0.02	
C15:1 Pentadecenoic	<0.02	%	0.02	
C16:0 Hexadecanoic (Palmitic)	21.67	%	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)	1.53	%	0.02	
C17:1 Heptadecenoic (Margaroleic)	<0.02	%	0.02	
C18:0 Octadecanoic (Stearic)	1.13	%	0.02	
C18:1 Octadecenoic (Oleic + isomers)	1.07	%	0.02	
C18:2 Octadecadienoic (Linoleic + isomers)	2.50	%	0.02	

		Results	Unit	LOQ	LOD
	C18:2 Octadecadienoic Omega 6 (Linoleic)	2.45	%	0.02	
	C18:3 Octadecatrienoic (Linolenic + isomers)	0.53	%	0.02	
	C18:3 Octadecatrienoic Omega 3 (Alpha Linolenic)	0.36	%	0.02	
	C18:3 Octadecatrienoic Omega 6 (Gamma Linolenic)	0.17	%	0.02	
	C18:4 Octadecatetraenoic Omega 3 (Stearidonic)	0.13	%	0.02	
	C20:0 Eicosanoic (Arachidic)	0.24	%	0.02	
	C20:1 Eicosenoic (Gondoic + isomers)	0.03	%	0.02	
	C20:2 Eicosadienoic Omega 6	0.02	%	0.02	
	C20:3 Eicosatrienoic	0.21	%	0.02	
	C20:3 Eicosatrienoic Omega 3	<0.02	%	0.02	
	C20:3 Eicosatrienoic Omega 6	0.21	%	0.02	
	C20:4 Eicosatetraenoic (Arachidonic + isomers)	0.65	%	0.02	
	C20:4 Eicosatetraenoic Omega 3	0.55	%	0.02	
	C20:4 Eicosatetraenoic Omega 6 (Arachidonic)	0.09	%	0.02	
	C20:5 Eicosapentaenoic Omega 3	0.33	%	0.02	
	C21:5 Heneicosapentaenoic Omega 3	<0.02	%	0.02	
	C22:0 Docosanoic (Behenic)	0.13	%	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	11.80	%	0.02	
	C22:5 Docosapentaenoic Omega 3	0.15	%	0.02	
	C22:5 Docosapentaenoic Omega 6	11.65	%	0.02	
	C22:6 Docosahexaenoic Omega 3	43.48	%	0.02	
	C24:0 Tetracosanoic (Lignoceric)	0.07	%	0.02	
	C24:1 Tetracosenoic (Nervonic)	<0.02	%	0.02	
	Sum of Omega 3 Isomers	45.00	%	0.05	
	Sum of Omega 6 Isomers	14.65	%	0.05	
	Total Fat as Triglycerides	91.07	%	0.1	
	Total Fatty Acids Calc.	87.38	%	0.1	
	Total Monounsaturated Fatty Acids	1.26	%	0.05	
	Total Polyunsaturated Fatty Acids	59.72	%	0.05	
	Total Saturated Fatty Acids	26.41	%	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 13.04-5 : 2013-08, mod.				
	Linuron	<0.01	mg/kg	0.01	
	Bromacil	<0.01	mg/kg	0.01	
	Pyrethrins	<0.1	mg/kg	0.1	
☆ UM5Y6	Aerobic Plate Count /ml AOAC 990.12 Method: AOAC 990.12				
	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 121501 Method: AOAC-RI 121501				

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

		Results	Unit	LOQ	LOD
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 1,071 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 (0.06)	(a) Captan (0.06)	(a) Captan/THPI (Sum calculated as Captan) ()	(a) Carbophenothion (0.05)	(a) Carbophenothion-methyl (0.05)	(a) Carboxin (0.06)
(a) Chlorbenside (0.06)	(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) Diclofop (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) 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 (0.06)	(a) Metribuzin (0.04)	(a) Mevinphos (0.02)
(a) Mirex (0.01)	(a) N-Desathyl-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 (0.06)	(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 (0.06)
(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) 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

Ally Dong	Claire Wang	Jack He
Authorized Signatory	Authorized Signatory	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

For and on behalf of Eurofins Technology Service (Suzhou) Co., Ltd

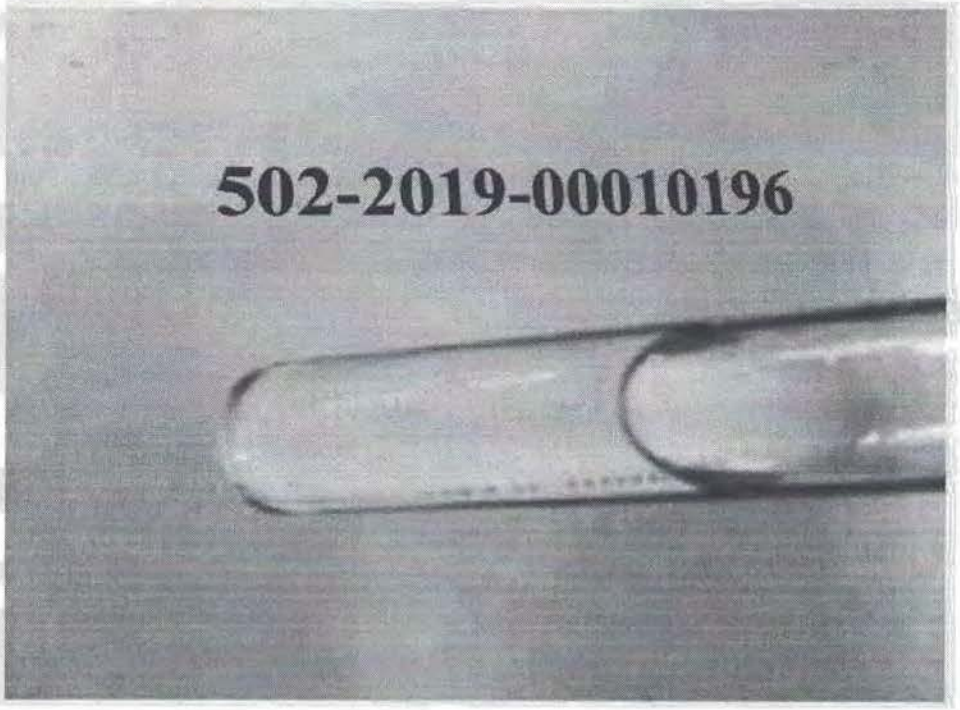
END OF REPORT

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

Physical inspection

Sample code	502-2019-00010196
Sample name	DHA oil
Color	Bright 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 +86 400 826 5088
Fax +86 512 6878 5966
www.eurofins.cn

Appendix B,

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)

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: strain identification report -- Morphological characteristics of microbial strains

1.DHF （Algae）

Detection result:

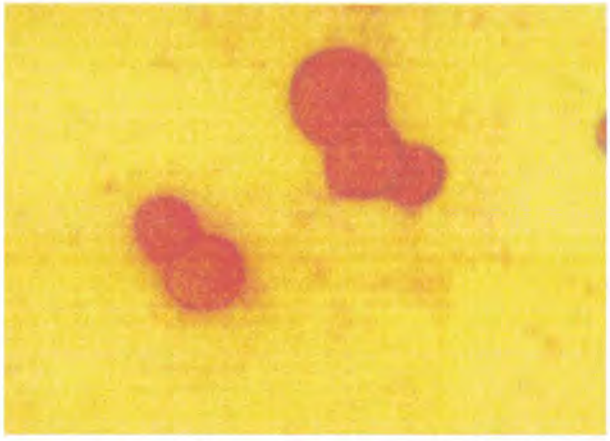


Figure 1. Microscope photographs of DHF

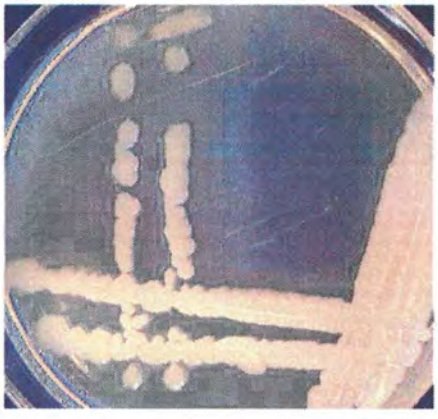


Figure 2. DHF Flat colony positive observation photograph

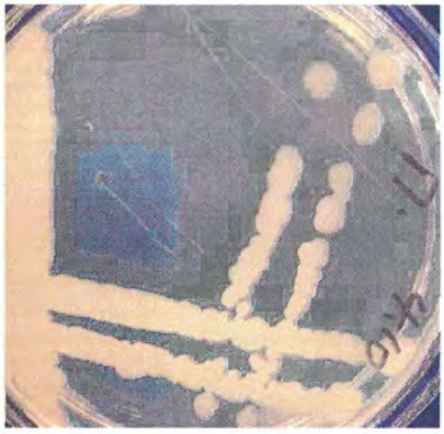


图 3. DHF Observations of flat colonies on the reverse side

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.

TOXICOLOGY STUDY REPORT

Title of Study	Mutagenicity Study of DHA
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 [redacted]
Contact Tel. and E-mail	86-15854569558; gylbill@163.com; gaoyonglin@ytu.edu.cn.
Study Director	Yonglin Gao
Study Participants	Yonglin Gao *Operator* Meina Wang, Bing Han *Test products management*
Study Start and End Dates	Mar. 2019

CONTENTS

List of Tables

Mutagenicity Study of DHA

ABSTRACT

As a part of a safety evaluation, we evaluated the potential mutagenicity of DHA using a bacterial reverse mutation assay. Five strains of *Salmonella typhimurium* (TA97, TA98, TA100, TA102, and TA1535) were treated with DHA 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, up to 100 μl/plate (the maximum concentration), was non-mutagenic under the conditions used in this test.

Keywords: DHA; Bacterial reverse mutation assay

1. Study design

As a part of a safety evaluation, we evaluated the potential mutagenicity of DHA 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.

2. 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 DHA did not show any antibacterial activity up to the maximum concentration, 100 μl/plate. TA97, TA98, TA100, TA102, and TA1535 were treated with DHA 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	NaN3 (1.5)
	+S9	2-AF (60.0)
TA102	-S9	MMC (1.0)
	+S9	1,8-DT (50)
TA1535	-S9	NaN3 (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 in bacteria was evaluated up to a maximum dose of 100 μl/plate using the plate incorporation method (Table 2, 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 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	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	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.

5. Conclusion

Under our test conditions, a reverse mutation assay using five strains of *Salmonella typhimurium* (TA97, TA98, TA100, TA102, and TA1535), DHA (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 was non-mutagenic under the conditions used in this test.

Appendix D.

TOXICOLOGY STUDY REPORT

Title of Study	Oral Acute Toxicity Study of DHA in Rats
Study Number	A2019-T002
Entrustment Company	NutraSource, Inc.
Address of Entrustment Company	NutraSource, Inc. 6309 Morning Dew Ct, Clarksville, MD 21029
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 [redacted]
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

Contents

List of Tables and Figures

Oral Acute Toxicity Study of DHA in Rats

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 DHA after oral administration in rats. The test substances were administered to young rats by oral gavage at doses of 0 (control), 1.0 ml/kg body weight (BW), 2.0 ml/kg BW, 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 DHA was above 4.0 ml/kg BW (the maximum dose volume) in both male and female rats.

Key words: DHA; Acute Toxicity Study; Rat

1. 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. DHA was administered by oral gavage to rats (0, 1.0 ml/kg BW, 2.0 ml/kg BW, and 4.0 ml/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, 1.0 ml/kg BW, 2.0 ml/kg BW, and 4.0 ml/kg BW DHA (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	Number of animals
1	0 (Control)	10 (♀:5+♂:5)
2	1.0 ml/kg BW DHA	10 (♀:5+♂:5)
3	2.0 ml/kg BW DHA	10 (♀:5+♂:5)
4	4.0 ml/kg BW DHA	10 (♀:5+♂:5)

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

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.

7. Results

7.1 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 2,3 and Figures 1,2, there were no significant differences in body weight between the DHA treated groups and the control group.

7.2 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 4,5; Figures 3,4) between the DHA treated groups and the control group.

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

The organ/body weight ratios (the organ coefficient) are shown in Tables 6,7 and Figures 5,6. No consistent, statistically significant, or dose-dependent adverse effects were observed in all groups. On macroscopic examination, there are no treatment-related effects noted in these tissues.

8. Conclusion

Under our test conditions, the acute oral LD_{50} for DHA was above 4.0 ml/kg BW (the maximum dose volume) in both male and female rats.

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

Groups	Test substance	Before	1st week	2nd week
1	0 (Control)	99.60±1.82	138.00±4.85	164.60±8.17
2	1.0 ml/kg BW DHA	100.60±2.41	140.80±10.76	166.20±5.85
3	2.0 ml/kg BW DHA	98.80±1.79	138.40±6.02	169.20±8.41
4	4.0 ml/kg BW DHA	100.80±2.77	137.00±3.32	163.40±7.92

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

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

Groups	Test substance	Before	1st week	2nd week
1	0 (Control)	104.80±3.77	148.20±4.66	204.00±4.95

2	1.0 ml/kg BW DHA	103.00±4.30	150.20±7.26	206.60±8.29
3	2.0 ml/kg BW DHA	102.60±3.97	151.40±9.48	210.60±7.80
4	4.0 ml/kg BW DHA	103.80±3.27	149.60±6.11	203.20±5.81

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

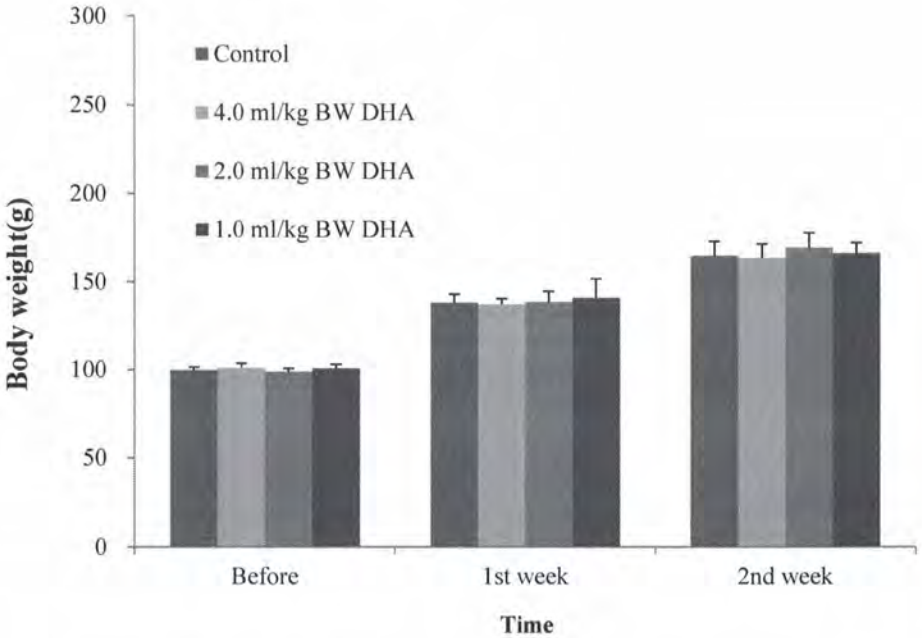


Figure 1. Body weight change of female rats during a 14-day study

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

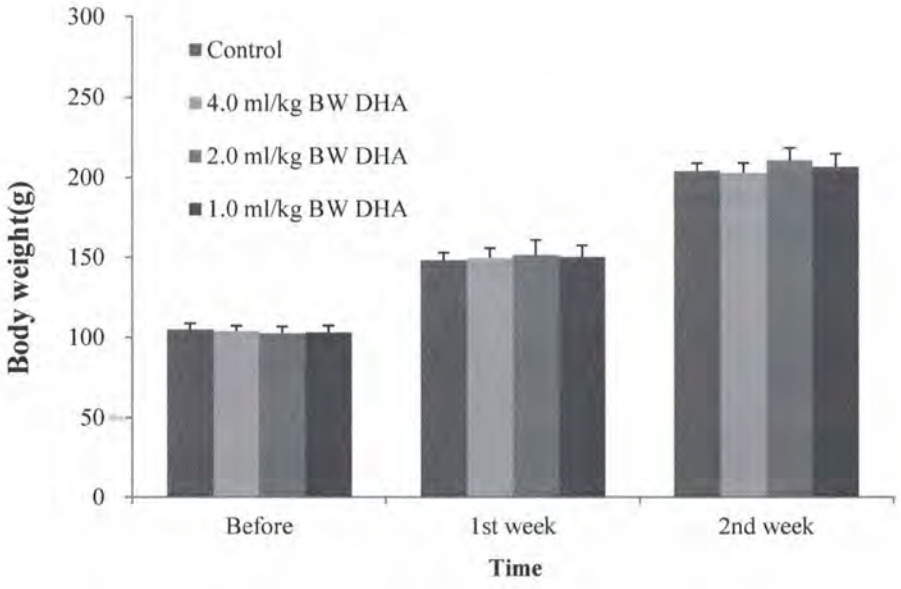


Figure 2. Body weight change of male rats during a 14-day study

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

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

Groups	Test substance	1st week	2nd week
1	0 (Control)	11.98±1.02	11.30±1.08
2	1.0 ml/kg BW DHA	12.12±1.90	11.52±1.72
3	2.0 ml/kg BW DHA	12.12±1.57	11.82±0.66
4	4.0 ml/kg BW DHA	12.30±1.78	12.01±0.79

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

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

Groups	Test substance	1st week	2nd week
1	0 (Control)	11.76±1.36	11.36±0.50
2	1.0 ml/kg BW DHA	11.79±1.09	11.19±0.84
3	2.0 ml/kg BW DHA	11.71±1.26	10.87±0.66
4	4.0 ml/kg BW DHA	12.04±1.79	11.13±1.14

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

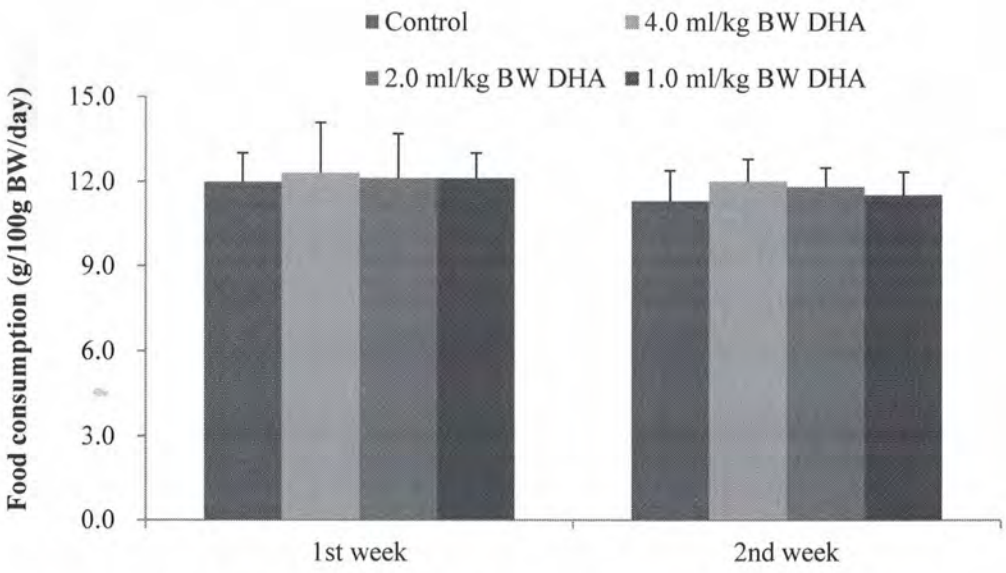


Figure 3. Food consumption of female rats during a 14-day study

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

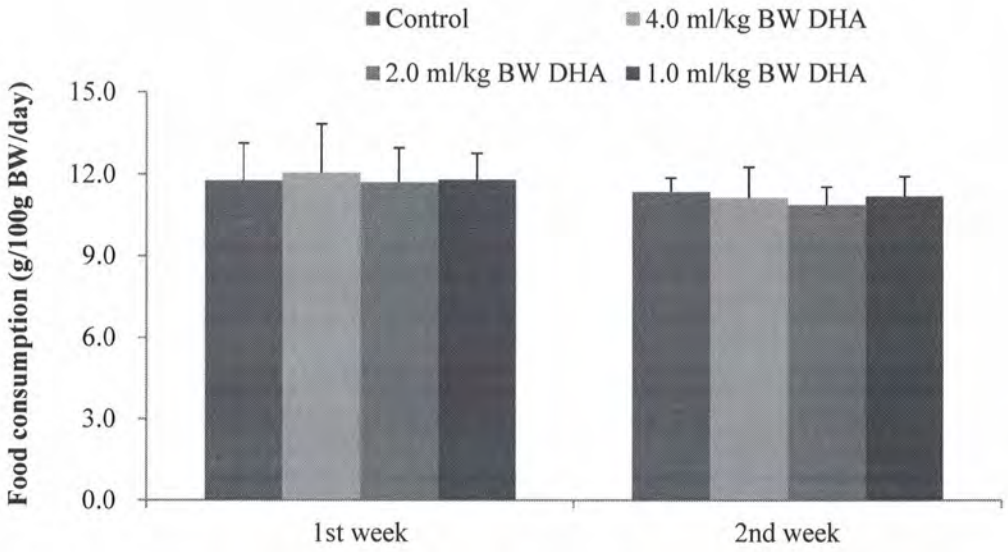


Figure 4. Food consumption of male rats during a 14-day study

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

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

	0 (Control)	1.0 ml/kg BW DHA	2.0 ml/kg BW DHA	4.0 ml/kg BW DHA
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)	1.0 ml/kg BW DHA	2.0 ml/kg BW DHA	4.0 ml/kg BW DHA
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.

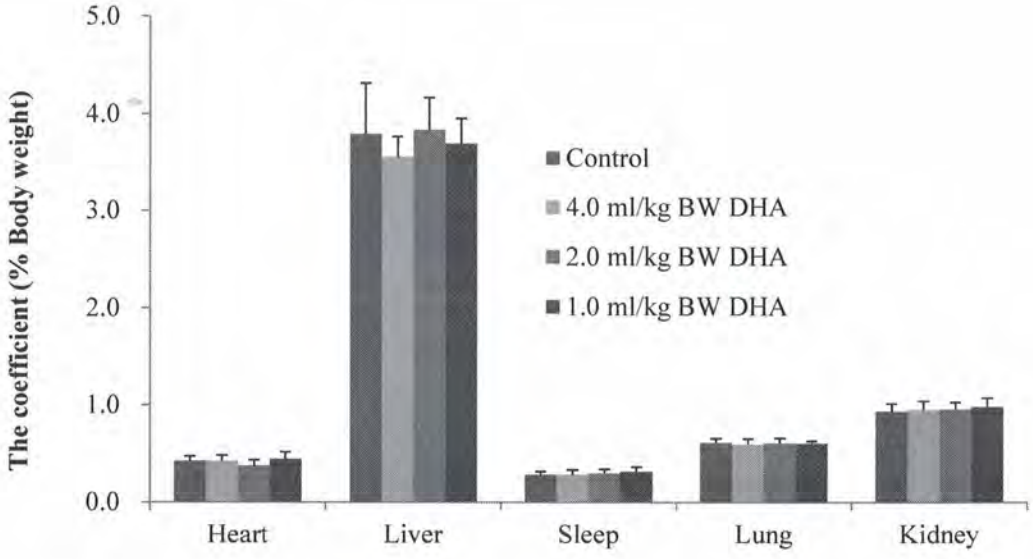


Figure 5. The organ coefficient of female rats after a 14-day study

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

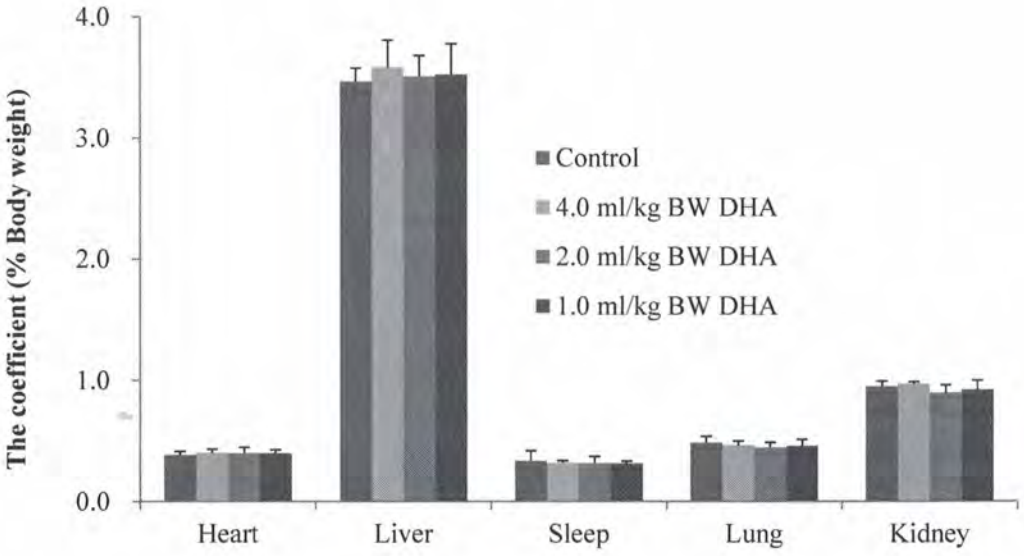


Figure 6. The organ coefficient of male rats after a 14-day study

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

From: Susan S Cho
To: Morissette, Rachel
Subject: Re: information regarding GRN 000860 - response requested
Date: Tuesday, August 20, 2019 11:29:49 AM
Attachments: image002.png

Thank you. On behalf of Hubei Fuxing Biotechnology, we request that FDA ceases to evaluate the notice.
Thank you.

Sincerely,
Susan Cho
NutraSource

Sent from Yahoo Mail for iPhone

On Tuesday, August 20, 2019, 10:40 AM, Morissette, Rachel <Rachel.Morissette@fda.hhs.gov> wrote:

> Dear Dr. Cho,
>
> After reviewing Hubei Fuxing BioTechnology's GRAS Notice GRN 000860, our review team has identified a large number of errors and discrepancies throughout all sections of the notice. A broad description of these errors includes:
>
> Incorrect references and citations to both GRNs and the literature
>
> Inaccurate or missing information on the intended use, identify, manufacturing, specifications, and exposure
>
> Inaccurate descriptions of presented studies
>
> Incorrect reporting of NOAEL values
>
> Incorrect or inconsistent unit usage
>
> Typos throughout the notice impacting the notice's readability
>
> Due to the poor quality of this submission, we strongly recommend that Hubei Fuxing BioTechnology requests that we cease our evaluation of GRN 000860. After Hubei Fuxing BioTechnology requests that we cease to evaluate its notice, we will provide a detailed list of the deficiencies identified in GRN 000860. If Hubei Fuxing BioTechnology chooses not to request that we cease our evaluation of GRN 000860, then we will issue a no basis letter for this GRAS notice.

Please provide your response within 10 business days.

Sincerely,

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:	Morissette, Rachel
To:	Susan S Cho
Bcc:	Wafula, Denis; Honigfort, Mical
Subject:	follow-up with list of deficiencies for GRN 000860
Date:	Wednesday, August 21, 2019 2:30:00 PM
Attachments:	08-21-19 GRN000860 Questions for Notifier.pdf image013.png image024.png image035.png

Dear Dr. Cho,

Please see attached a list of the deficiencies we identified for GRN 000860 for your information. No response to these questions is required as we have ceased to evaluate this notice at your request. Dr. Susan Carlson (Division Director, OFAS/Division of Food Ingredients (DFI)) and Dr. Mical Honigfort (Branch Chief, Regulatory Review Branch, DFI) will be reaching out to you in the near future for a follow-up meeting. Please review these deficiencies in preparation for this meeting.

In the meantime, I will be preparing the Cease-to-Evaluate letter and will send that to you as soon as possible.

Sincerely,

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

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Susan S Cho <susanscho1@yahoo.com>
Sent: Tuesday, August 20, 2019 12:35 PM
To: Morissette, Rachel <Rachel.Morissette@fda.hhs.gov>
Subject: Re: information regarding GRN 000860 - response requested

Dear Dr. Morissette,

We would appreciate it if you would provide a detailed list of deficiencies. Thank you

Sincerely,

Susan
On Tuesday, August 20, 2019, 11:31:34 AM EDT, Morissette, Rachel <Rachel.Morissette@fda.hhs.gov> wrote:

Thank you.

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, August 20, 2019 11:28 AM
To: Morissette, Rachel <Rachel.Morissette@fda.hhs.gov>
Subject: Re: information regarding GRN 000860 - response requested

Thank you. On behalf of Hubei Fuxing Biotechnology, we request that FDA ceases to evaluate the notice.

Thank you.

Sincerely,

Susan Cho

NutraSource

Sent from Yahoo Mail for iPhone

On Tuesday, August 20, 2019, 10:40 AM, Morissette, Rachel <Rachel.Morissette@fda.hhs.gov> wrote:

> Dear Dr. Cho,

After reviewing Hubei Fuxing BioTechnology's GRAS Notice GRN 000860, our review team has identified a large number of errors and discrepancies throughout all sections of the notice. A broad description of these errors includes:

Incorrect references and citations to both GRNs and the literature

Inaccurate or missing information on the intended use, identify, manufacturing, specifications, and exposure

Inaccurate descriptions of presented studies

Incorrect reporting of NOAEL values

Incorrect or inconsistent unit usage

Typos throughout the notice impacting the notice's readability

Due to the poor quality of this submission, we strongly recommend that Hubei Fuxing BioTechnology requests that we cease our evaluation of GRN 000860. After Hubei Fuxing BioTechnology requests that we cease to evaluate its notice, we will provide a detailed list of the deficiencies identified in GRN 000860. If Hubei Fuxing BioTechnology chooses not to request that we cease our evaluation of GRN 000860, then we will issue a no basis letter for this GRAS notice.

Please provide your response within 10 business days.

Sincerely,

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

August 21, 2019

Dear Dr. Cho,

After reviewing Hubei Fuxing BioTechnology, Co., Ltd. (Hubei Fuxing)'s GRAS Notice GRN 000860 for the intended use of algal oil (≥36% docosahexaenoic acid) from *Schizochytrium* sp. strain DHF (algal oil (≥36% DHA)), we noted the following deficiencies.

General:

1. The intended use in the notice describes algal oil (≥36% DHA) as a "nutritional food ingredient." As health claims or benefits are not considered in a safety evaluation of a GRAS notice, we would not refer to an ingredient as "nutritional". Please provide a statement removing the term "nutritional" from the intended use.

2. The notice refers to two different date ranges for the literature search that was conducted. Please clarify when an updated literate search was conducted.

3. While Hubei Fuxing incorporates into the notice data and information from seven prior GRAS notices, the notice also references 11 other prior GRAS notices non-specifically. It is unclear how all of these prior notices support the safe use of Hubei Fuxing's product or what specific data and information is being referred to in these prior notices. Please revise the safety narrative in Part 6 to specifically indicate how the prior GRAS notices support the safe use of the ingredient, or else remove reference to extraneous notices in a revised narrative.

4. Hubei Fuxing states the following in the notice:

   > "The intended use level of DHA-rich oil is similar to or same as all other approved uses for incorporation of DHA in infant formula (GRNs 553, 667, 730, and 776)."

   The subject of GRN 000667 is rebaudioside M for use as a general purpose sweetener in foods, other than infant formula and meat and poultry products, and as a table top sweetener. Please clarify how GRN 000667 relates to the current notice.

5. On page 6 of the notice, Hubei Fuxing references GRN 000730 in a discussion about DHA. However, the subject of GRN 000730 is ARA-rich oil. Please clarify how this relates to the DHA discussion mentioned in that paragraph.

6. Please clarify if the exempt infant formula intended use category is for pre-term infants only.

7. Amino acid-based infant formulas are listed in the notice as "non-exempt." However, they are considered exempt infant formulas. Please provide a statement correcting this information.

8. Hubei Fuxing mentions an intended use in "hydrolyzed protein based formulas." Please clarify if this refers to partially-hydrolyzed or extensively-hydrolyzed formulas.

If the latter, extensively-hydrolyzed, protein-based infant formulas are considered exempt formulas.

9. Are the maximum use levels indicated as consumed or is the algal oil (≥36% DHA) intended for use in infant formulas that are ready-to-use or those that must be reconstituted?

10. In Appendix D in Figure 5 on page 14 and Figure 6 on page 15, the word "sleep" is used to designate the organ "spleen" for the %bw or the organs in relation to the amount of DHA. Please clarify.

Chemistry:

11. The notice describes algal oil (≥36% DHA) as a "free flowing, yellow oil." Please indicate if this product is intended to impart color and be used as a color additive.

12. Please provide a comparison of the fatty acid profile for algal oil (≥36% DHA) to the Food Chemicals Codex specifications for fatty acid composition of DHA algal oil (*Schizochytrium* sp.).

13. Hubei Fuxing provides analyses of five non-consecutive lots of algal oil (≥36% DHA) for dioxans, furans, and domoic acid (amnesic shellfish poison) where the methods of analysis are listed as internal methods. Please discuss how these internal methods have been validated.

14. In Table 17, Hubei Fuxing compares the levels of sterols/stanals in algal oil (≥36% DHA) to the levels of sterols/stanals in algal oils from GRNs 000553, 000677, and 000776. However, the units in Table 17 are in wt% relative to the algal oil. The units for individual sterols/stanols for the other GRNs are in wt% of total sterols/stanols. Please standardize the units so that the values in Table 17 can be directly compared to the values reported in the referenced GRNs.

15. In Table 9, the regulatory status of potassium sulfate is listed under 21 CFR 184.1643. However, the regulation is only for use as a flavoring agent or adjuvant in nonalcoholic beverages. Please provide a scientific rationale for whether there is expected to be residual potassium sulfate in the algal oil (≥36% DHA) final product or provide further regulatory justification for this intended use.

16. In Table 9, the regulatory status of corn syrup powder (corn steep liquor) is listed as 21 CFR 184.1033. However, this is the regulation for citric acid. Please provide the regulatory status of your raw material termed "corn syrup powder (corn steep liquor)".

17. In Table 9, the regulatory status of malic acid is listed under 21 CFR 184.1069. However, the regulation does not specifically apply to use in infant formula. Please provide a scientific rationale for whether there is expected to be residual malic acid in the algal oil (≥36% DHA) final product or provide further regulatory justification for this intended use.

18. In Table 10, the CAS number for activated carbon is shown as 4808-60-7, which is the CAS number for quartz. Please provide the correct CAS number for activated carbon.

19. In Table 10, the regulatory status of tocopherols is listed under 21 CFR 184.1890. In this notice, tocopherols are being used as an antioxidant. However, 21 CFR 184.1890 only allows for the use of tocopherols as a preservative in pump cured bacon. Please provide the regulatory status of tocopherols for Hubei Fuxing's intended use as an antioxidant.

20. In the manufacturing flow diagram (Figure 2), one of the manufacturing steps is described as "debonging". Please clarify what "debonging" means.

21. In Table 12, the specification for *Salmonella* lists the method of analysis as AOAC-RI 121501. However, we were not able to identify this method. Please provide a brief description of the method, how it was validated, and/or an updated reference.

22. While there are batch analysis data provided in the notice for *Cronobacter* spp., a specification was not provided in Table 12. Please provide this specification in the table.

23. Two of the lots do not meet the specification for acid value of ≤0.5 mg KOH/g (lots D18071101J and D181122701J). Please clarify this discrepancy.

24. For conventional foods, Hubei Fuxing does not indicate the populations that its exposure estimates cover in the notice. Please indicate the populations covered by the exposure estimates.

25. Hubei Fuxing cites GRN 000137 for the exposure to DHA of 1.4 g/p/d and discusses that FDA has determined that DHA may be used in combination with EPA up to 3 g/p/d. However, Hubei Fuxing does not cite a reference. Please include the reference for the total exposure to DHA and EPA. We note that Hubei Fuxing cites several previous GRNs in the intended use discussion to demonstrate that these uses are substitutional. However, it is unclear whether Hubei Fuxing's exposure estimates are still current.

26. Hubei Fuxing states that there are no known self-limiting levels of use for DHA in infant formula and that the ratio of ARA and DHA is expected to be 2:1 to 1:1. The ratio of ARA to DHA is not a self-limiting level of use. Please clarify in the discussion what limits the use of DHA (thereby limiting the use of the algal oil (≥36% DHA)) to a maximum of 0.5 % of total fat in infant formula.

Toxicology:

27. On page 34 (section 6.B.3.), Hubei Fuxing states that rats were administered algal oil "by oral gavage at doses of 0, 1.0, 2.0, or 4.0 mL/kg body weight (bw)". Please provide dose levels in units of mg/kg bw.

28. On page 35, Hubei Fuxing states "For DHA-rich algal oils, the NOAELS, established from subchronic toxicity studies, ranged from 3,258 to 5,000 mg/kg bw/day in rats".

    a. Please note that in the subchronic toxicity study by Fedorova-Dahms et al. (2011a), the NOAEL for males was 3,149 mg/kg bw/day; hence, the correct range is 3,149 to 5,000 mg/kg bw/day. Please verify.

b. For the above NOAEL range, one of the articles cited is Hammond et al., 2001a. Please note that the test article in this study is DRM (DHA-rich microalgae) and not DHA-rich algal oil. Please verify. (Full reference: Hammond, B. G., Mayhew, D. A., Naylor, M. W., Ruecker, F. A., Mast, R. W., & Sander, W. J. (2001). Safety assessment of DRM from Schizochytrium Sp.: I. Subchronic rat feeding study. Regulatory Toxicology and Pharmacology, 33(2), 192-204.)

29. On page 35, Hubei Fuxing states "From developmental toxicity studies, the NOAELs were in the range of 2,000 to 5,000 mg/kg bw/day for rats and 1,800 mg/kg bw/day in NZW rabbits" for DHA-rich algal oil. Please note that the test material for the rabbit study was DRM and not DHA-rich algal oil; hence, this result belongs in 5) and not 3) on page 35 of the GRAS notice. Please verify.

30. On page 35, Hubei Fuxing reports NOAEL ranges for 1) subchronic toxicity studies for DHA-rich algal oil, 2) subchronic and/or reproductive studies for DHA-rich algal oil, 3) developmental toxicity studies for DHA-rich algal oil, 4) DHA ethyl ester, and 5) DRM. Please note that in Table 19 Hubei Fuxing presents the following result: Hammond et al., 2001b, reported a maternal NOAEL of 600 mg/kg bw/day (LOAEL of 1,800 mg/kg bw/day).

    a. Please account for this result in one of the above NOAEL ranges.

    b. Please note that the test material in this study was DRM and not DHA-rich algal oil that Hubei Fuxing reported. Please verify.

31. On page 36 in Table 19, Hubei Fuxing states that in the "acute oral toxicity (gavage)" study by Schmitt et al. (2012a), the duration of administration was 14 days. We note that rats received a single dose and were monitored for 14 days thereafter. Please verify.

32. On page 37 in Table 19, Hubei Fuxing states that the duration of the "developmental toxicity of mothers" study (Fedorova-Dahms et al., 2011b) had a duration of 15 days and a NOAEL of 4,260 mg/kg bw/day.

    a. According to the article (section 2.3.2 Study design), "parental males and females received the experimental diet while housed separately for a 28-day premating period, followed by feeding through a 14-day co-habitation period. Upon determination of pregnancy or following the prescribed 14-day mating period, females were removed to a separate cage and fed through the gestation period of pregnancy and day 22 of lactation." Please state the correct duration of experimental diet administration for the mothers.

    b. Please note that while Hubei Fuxing states that it provided the NOAEL for this study for the "mothers", the NOAEL that was provided in the notice is actually an average NOAEL for both sexes of the F1 generation (see pages 3314 (Table 3) and 3317 of the article). Please report the correct NOAEL for the mothers (see page 3314 (Table 3) of the article). Additionally, Hubei Fuxing may also report the NOAEL for the fathers (see page 3314 (Table 3)), in which case the duration of administration for the fathers should be reported as well.

c. Please note that the study for mothers and fathers was a combined subchronic and reproductive toxicity study and not a "developmental toxicity of mothers". Please verify.

33. In Table 19, for some studies separate NOAEL values are available for males and females from the referenced publications. For some of these studies, Hubei Fuxing reports the NOAELs for both sexes separately, while for other studies Hubei Fuxing reports an average value of the NOAELs for both sexes, even though the individual value for each sex is available. The fact that the NOAELs for both sexes are averaged for some of the studies is not noted. It is also not clear why the NOAELs are averaged for some studies and why NOAEL values for both sexes are reported separately in others.

    a. For future reference, please be consistent with reporting results.

    b. Please state what the male and female NOAELs are for the 90-day study for the F1 generation for the Fedorova-Dahms et al. (2011b) study.

    c. Please state what the male and female NOAELs are for the 90-day study for the Fedorova-Dahms et al. (2011a) study.

34. In Table 19 (DHA-rich oil section) for the Hammond et al. (2001b) study in rabbits, Hubei Fuxing states that it is a "developmental toxicity" study of DHA-rich oil with a duration of administration of 30 days with a maternal NOAEL of 600 mg/kg bw/day and a developmental NOAEL of 1,800 mg/kg bw/day. Additionally, Hubei Fuxing states that "high-dose (1,800) DHA oil and fish oil groups: F0 reduced food consumption and body weight" were the only observations in the study.

    a. Please note that this study was a combined reproductive and developmental toxicity study. Mothers were treated only for 13 days (GD 6 through GD 18) (page 207 of the article) and not 30 days. Please verify.

    b. While this rabbit study was in the DHA-rich oil section of the table and not in the DRM section, the test article was the dried powder of the microalgae itself and not the oil extracted from the microalgae. Please verify.

    c. According to the article, in addition to "reductions in food consumption and body weight gain a slight increase in abortions occurred in the fish oil control and the 1,800 mg/kg bw/day" algal oil group (pages 205 and 216 of the article). On page 214 of the article, the study authors state that "the abortions may also be secondary to the significant dietary disruption in the fish oil and 1800 mg/kg/day DRM groups. Marked and sustained reduction in food consumption during the prenatal period can disrupt normal development and/or maintenance of pregnancy." Moreover, the authors go on stating that "The fact that the fish oil control group experienced an abortion rate similar to the 1800 mg/kg/day DRM group suggests that the presence of higher levels of dietary fat probably contributed to the reductions in food consumption and corresponding abortions in these groups." As all adverse effects should be reported in a safety narrative, please discuss the increase in abortions, which is test-article related.

35. In Table 19 (DRM section) for the Hammond et al. (2001b) study in rats, Hubei Fuxing states that the duration of administration was 15 days. Please note that the rats were

administered DRM only on gestation days 6-15 (see page 205 of the article). Please state the correct number of days for which the test article was administered.

36. In Table 19 (DHA-rich oil section), Hubei Fuxing summarizes the results of the 13-week Hammond et al. (2001a) study in rats at dose levels of 400, 1,500, and 4,000 mg/kg bw/day. Please note that the test article in this study was dried powder of the microalgae itself (DRM) and not the oil extracted from the microalgae. Consequently, this study belongs in the DRM section of the table and not the DHA-rich oil section. Please verify the identity of the test article.

37. In Table 19 (DRM section), Hubei Fuxing summarizes the results of a 13-week single-generation reproduction study in rats by Hammond et al. (2001c) at dietary levels of 0.6, 6.0, and 30%.

    a. Please note that according to the article (page 357) "F0 males were treated for 70 days prior to mating, during mating, and for approximately 3 weeks following mating. F0 females were treated for 2 weeks prior to mating, during mating, and throughout gestation and lactation." In Table 1 of the article (page 358), it is also clearly shown that males were treated for more than 13 weeks (please see Table 1). Please state the correct durations of administration for males and females in units of either days or weeks.

    b. For this study, Hubei Fuxing states that the NOAEL for DHA for males is 1,500 mg/kg bw/day and for females is 1,800 mg/kg bw/day. According to the article (page 358, beginning of Results section), these values are 1,512 and 1,680 mg/kg bw/day, respectively. Please verify.

    c. For this study, Hubei Fuxing states that the NOAEL for DRM for males is 17,847 mg/kg bw/day and for females is 21,000 mg/kg bw/day. The correct value for females is 20,669 (please see table 1 on page 358). Please verify.

        i. We note that for most study results reported in the notice, Hubei Fuxing reports exact NOAEL values, while for others rounded values are provided even when the exact values are available. Please report study results consistently in the notice.

38. In Table 19, Hubei Fuxing discusses studies mentioned in the Schmitt et al. (2001b) article.

    a. Regarding the study with a study design stated as "developmental toxicity (gavage)" with a duration of 20 days:

        i. According to the article, the "DHA-rich algal oil was administered orally by gavage to pregnant Crl:CD(SD) rats during gestation days 6–19." Please verify and provide the exact number of days for which the test article was administered.

        ii. For this study, Hubei Fuxing reports a NOAEL of 2,000 mg/kg bw/day. Please clarify if this is the maternal or embryo/fetal development NOAEL or the NOAEL for both.

b. Regarding the study with a study design stated as "subchronic and reproductive toxicity of first generation (diet)" with a duration of 75-90 days for both sexes:

    i. According to the article "F0 males and females were exposed for 89–91 and 75–77 consecutive days, respectively." Please verify.

c. Regarding the study with a study design stated as "developmental and subchronic toxicity of second generation (diet)" with a duration of 106-111 days for both sexes:

    i. According to the article, "F1 males and females were exposed for 106–107 and 110–111 consecutive days, respectively." Please verify.

39. In Table 19, for the Falk et al. (2017) study, please state whether the NOAEL provided is for maternal toxicity, embryo/fetal development, and/or for paternal or maternal treatment-related reproductive toxicity.

40. In Table 19, for the Abril et al. (2003) study, Hubei Fuxing reports a NOAEL of 1,368 mg/kg bw/day for DRM and a NOAEL of approximately 305 mg/kg bw/day for DHA. According to the article (page 79), "Overall study averages for consumption of DRM were 2.680, 1.169, 3.391, and 5.745 kg DRM per pig for treatment groups 1, 2, 3, and 4, respectively. Using the value of DHA content in DRM (22.3% DHA on a dry weight basis), actual intake of DHA in treatment group 1 averaged 598 g DHA per pig over the course of 120 days, a whole-life exposure to DRM. Treatment groups 2, 3, and 4 averaged 261, 756, and 1281 g of DHA per pig, respectively, delivered in the form of DRM during the last 42 days of the study." Please clearly explain where the NOAEL of 1,368 mg/kg bw/day for DRM and a NOAEL of approximately 305 mg/kg bw/day for DHA came from. Please show any calculations, if any.

41. Based on the responses to all of the above questions, please correct the reported NOAEL ranges on page 35 a) through e).

42. In Part 6 of the notice, for some authors Hubei Fuxing cites more than one paper for the same year. For example: 1) Fedorova-Dahms et al., 2011a and Fedorova-Dahms et al., 2011b, and 2) Hammond et al., 2001a, Hammond et al., 2001b, and Hammond et al., 2001c. In Part 7 of the notice, while Hubei Fuxing provides the full references for all of these articles, Hubei Fuxing does not identify which references are a, b, and c. Please provide the full references for the above articles clearly indicating whether they are a, b, or c.

43. On page 41, Hubei Fuxing states that "The studies reviewed in these notifications supported the safe use of DHA in infant formula up to 0.96% of total fatty acids." This statement is also repeated on pages 47 and 49 slightly rephrased. Please provide this level in units of mg DHA/kg bw/day.

Sincerely,

Rachel Morissette, Ph.D.
Regulatory Review Scientist
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
Division of Food Ingredients