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February 21, 2020

Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740-3835

Subject: GRAS Notification – DHA Algal Oil

Dear Sir:

On behalf of Mara Renewables Corporation, ToxStrategies, Inc. (its agent) is submitting, for FDA review, a copy of the GRAS notification as required. The enclosed document provides notice of a claim that the food ingredient, DHA algal 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, for addition to food.

If you have any questions or require additional information, please do not hesitate to contact me at 630-352-0303, or dschmitt@toxstrategies.com.

Sincerely,

Donald F. Schmitt, M.P.H.
Senior Managing Scientist

ToxStrategies, Inc., 931 W. 75th St., Suite 137, PMB 255, Naperville, IL 60565
Office (630) 352-030 • www.toxstrategies.com

GRAS Determination of DHA Algal Oil for Use in Foods

FEBRUARY 7, 2020

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GRAS Determination of DHA Algal Oil for Use in Foods

SUBMITTED BY:

Mara Renewables Corporation
101A Research Drive
Dartmouth, NS B2Y 4T6
Canada

SUBMITTED TO:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
5100 Campus Drive
College Park MD 20740-3835

CONTACT FOR TECHNICAL OR OTHER INFORMATION

Donald F. Schmitt, MPH
ToxStrategies, Inc.
931 W. 75th St., Suite 137, PMB 255
Naperville, IL 60565

FEBRUARY 7, 2020

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Acronyms

CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations
CFU	colony-forming unit
cGMP	current Good Manufacturing Practices
COA	Certificate of Analysis
DHA	docosahexaenoic acid
DHASCO	docosahexaenoic acid single cell oil
EC	European Commission
EFSA	European Food Safety Authority
EPA	eicosapentaenoic acid
EU	European Union Organization
FCC	Food Chemicals Codex
FDA	U.S. Food and Drug Administration
FR	Federal Register
FSIS	Food Safety and Inspection Service
GMP	Good Manufacturing Practice
GRAS	Generally Recognized as Safe
GRN	GRAS Notification
HACCP	Hazard Analysis Critical Control Point
IOM	Institute of Medicine
JECFA	Joint FAO/WHO Expert Committee on Food Additives
NOAEL	no-observed-adverse-effect level
ONC	Ocean Nutrition Canada Limited
PUFA	polyunsaturated fatty acids
RBD	Refined, bleached, deodorized
QC	quality control
UL	tolerable upper intake level
USDA	U.S. Department of Agriculture
WHO	World Health Organization

§ 170.225 Part 1, GRAS Notice: Signed Statements and Certification

(1) GRAS Submission

Mara Renewables Corporation (Mara), through its agent ToxStrategies, Inc., hereby notifies the U.S. Food and Drug Administration (FDA) of the determination of a Generally Recognized as Safe (GRAS) notice for the use of docosahexaenoic acid (DHA)–rich algal oil in foods, in accordance with Subpart E of 21 CFR § 170.

(2) Name and Address

Mara Renewables Corporation
101A Research Drive
Dartmouth, NS B2Y 4T6
Canada

(3) Name of Notified Substance

The name of the substance that is the subject of this GRAS determination is DHA algae-sourced oil from the wild-type heterotrophic microalgae *Schizochytrium* sp. G3 (hereinafter referred to as G3).

(4) Intended Use in Food

The DHA algal oil is intended for use as a direct food ingredient in foods in accordance with current good manufacturing practice (cGMP).

(5) Statutory Basis for GRAS Determination

Mara, through its agent ToxStrategies, Inc., hereby notifies FDA of the submission of a GRAS notice for DHA algal oil, meeting the specifications described herein, which has been determined to be GRAS through scientific procedures in accordance with 21 CFR § 170.30(a) and (b).

(6) Premarket Approval Statement

Mara further asserts that the use of the DHA algal oil, as described below, is exempt from pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act, based on its conclusion that the substance is GRAS under the conditions of its intended use.

(7) Availability of Information

The data and information that serve as the basis for this GRAS determination, as well any information that has become available since the GRAS determination, will be sent on request, or are available for the FDA's review and copying during customary business hours from ToxStrategies, Inc., Naperville, IL. Please contact Donald F. Schmitt, ToxStrategies (agent for Mara), for all technical or regulatory information.

(8) Data and Information Confidentiality Statement

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

(9) GRAS Certification

To the best of our knowledge, the GRAS determination is a complete, representative, and balanced review. Mara is not aware of any information that would be inconsistent with a finding that the proposed use of the DHA-rich algal oil in foods, meeting appropriate specifications, and used according to cGMP, is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

(10) Name/Position of Notifier

02/21/2020
Date

Donald F. Schmitt, M.P.H.
Senior Managing Scientist
ToxStrategies, Inc.
Agent for Mara

(11) FSIS Statement

The data and information in the GRAS notice can be shared with the Food Safety Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA). The DHA algal oil will be used as an alternative edible oil in the production of various meat and poultry products at levels not to exceed 1.45% by weight of the product formulation for meat products and 0.87 % for poultry products.

§ 170.230 Part 2, Identity, Method of Manufacture, Specifications, and Physical or Technical Effect

Identity

The DHA product that is the subject of this GRAS determination is a liquid, white-to-orange oil that is extracted and refined from the wild-type heterotrophic microalgae *Schizochytrium* sp. G3 (hereinafter referred to as G3). It is a mixture of triglycerides containing mostly polyunsaturated fatty acids (PUFA) in which the predominant fatty acid (>35%) is DHA.

Empirical Formula and Chemical Structure of DHA

The empirical formula for DHA is $C_{22}H_{32}O_2$. The systematic name is 4,7,10,13,16,19-docosahexaenoic acid, and is often written as 22:6n-3 where the numbers indicate the number of carbon atoms in the molecule (22), the number of double bonds (6), and the number of carbon atoms from the methyl terminus to the first double bond (3). The molecular weight of DHA is 328.488 g/mol. The structural formula for DHA is represented below in Figure 1.

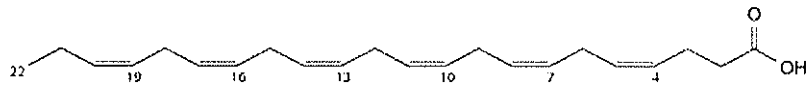

Figure 1. Structural formula of DHA

Common or Chemical Names

The preparation under consideration is referred to as DHA algal oil, DHA-rich algal oil, omega-3-rich algal oil, omega-3 algal oil, and algal oil. The CAS No. is 68424-59-9; glycerides, C14-C22 and C16-C22 unsaturated.

Characterization of Strain

Schizochytrium sp. are part of the human food chain, and they are consumed as a function of eating mussels and clams, as well as other marine organisms in general (Hammond et al., 2002). The *Schizochytrium* strain used is naturally occurring and not a product of genetic engineering. The microalgal family *Thraustochytriaceae* has historically comprised seven genera, *Japanochytrium, Schizochytrium, Ulkenia, Althornia, Diplophrys, Aplanochytrium,* and *Thraustochytrium*, all of which are referred to as thraustochytrids. The genera *Thraustochytrium, Schizochytrium,* and *Ulkenia* (oils from the latter two are the subject of previous authorizations under European Union [EU] novel food regulations and are GRAS [FDA, 2010, 2014a]) comprise marine protists commonly found in marine and estuarine environments.

The taxonomic structure of the family *Thraustochytriaceae* has been the subject of discussion and subsequent redistribution of some of the component organisms into a

broader suite of genera, including members of the genus *Schizochytrium* (Yokoyama and Honda, 2007a) and the genus *Ulkenia* (Yokoyama et al., 2007b). The *Schizochytrium* genus is part of the taxonomic *Thraustochytriaceae* family that is composed of several other genera. It is notable that the taxonomic classification within the *Thrausochytrids* has evolved over the years, in particular following the taxonomic rearrangement of the *Schizochytrium* genus proposed by Yokoyama and Honda (2007a) which resulted in the erection of two new genera (*Oblongichytrium* and *Aurantiochytrium*) and an amended description of the genus *Schizochytrium* (see Figure 2). In other words, the *Schizochytrium* genus was divided into three genera: *Schizochytrium*, *Oblongichytrium,* and *Aurantiochytrium*. A recent review relevant to this matter was published in 2018 by Marchan et al. (2017). As a consequence of this taxonomic evolution, some strains initially described as *Schizochytrium* today belong to *Aurantiochytrium* or *Oblongichytrium* genus: e.g., *Schizochytrium limacinum* and *Schizochytrium mangrovei* have been renamed as *Aurantiochytrium limacinum* and *Aurantiochytrium mangrovei,* respectively. The G3 strain is among these renamed strains, being recently classified as *Aurantiochytrium limacinum,* but previously known as *Schizochytrium limacinum*. It is common for the strain names to be used synonymously.

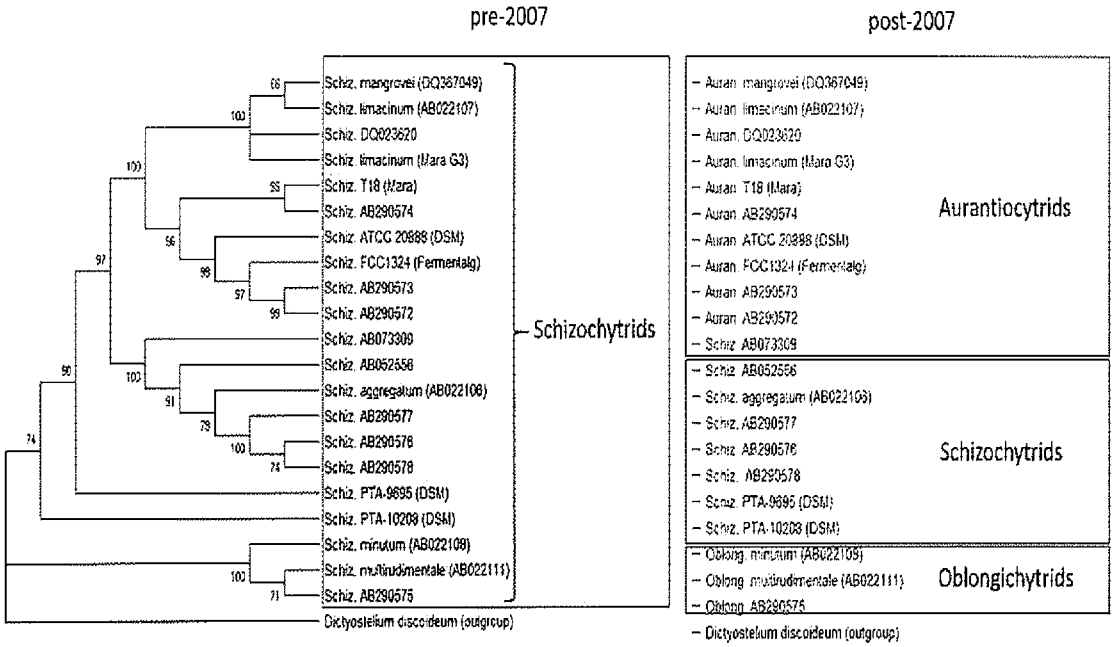

Figure 2. Genus *Schizochytrium* description

The possible presence of microalgae toxins produced by *Schizochytrium* sp. has been addressed, and the results can be found in Appendix A. Toxin production is unlikely, because there are no known reports of toxin production by thraustochytrids, of which *Schizochytrium* is a member (ONC, 2011; Hammond et al., 2002). G3 oil and biomass was

screened for the presence of toxins, including azaspiracids, pectenotoxins, okadaic acid, yessotoxins, and diarrhetic shellfish toxins (DSP), and none were detected (see Table 9).

Manufacturing Process

The following are descriptions of the processes used to manufacture the crude algal oil and then refine the DHA algal oil isolated from the fermentation process (see Figure 3). The process steps employed to refine the oil are essentially the same as those in GRN 677 and similar to those used in the refining of vegetable oils.

Figure 3. DHA algal oil manufacturing process

An oil rich in polyunsaturated fatty acids (PUFA) is produced by a heterotrophic fermentation process with a single-cell marine microalgae of the genus *Schizochytrium*, in particular, G3. The fermentation process uses a medium containing carbon and nitrogen sources, bulk and trace mineral nutrients, and vitamins (see Table 1). The microorganism G3 is maintained in cryopreserved culture vial and on nutrient agar plates before production. Following inoculation of the microorganism into a shake flask, the cultivation

process is scaled up through multiple stages of transfers, and finally into the production fermentation vessel. All vessels, pipelines, and fermentation media are put through a rigorous, timed, and controlled sterilization process prior to the transfer of the microorganism. The fermentation is carried out under axenic conditions (i.e., only one organism present—G3). During the fermentation process, more sterile carbon substrate (e.g., dextrose syrup) is added to the fermenter to allow higher cell growth and more oil synthesis. Operating parameters such as temperature, pH, aeration, and agitation are controlled throughout the process to ensure that results, in terms of cell growth, oil synthesis, and the oil's fatty acid profile, are reproducible. The vessel is operated under positive pressure to prevent any contamination by foreign organisms.

Table 1. Fermentation medium ingredients

Ingredient	**CFR Citation**
Water	--
Dextrose	21 CFR § 184.1857, 184.1865, 184.1866
Soy peptone	21 CFR § 184.1553
Yeast extract	21 CFR § 184.1983
Ammonium sulfate	21 CFR § 184.1143
Monosodium glutamate (MSG)	21 CFR § 182.1500
Sodium chloride	21 CFR § 182.1
Magnesium sulfate heptahydrate	21 CFR § 184.1443
Potassium phosphate monobasic	21 CFR § 175.105
Potassium phosphate dibasic	21 CFR § 182.6285
Ferric chloride	21 CFR § 184.1297
Calcium chloride	21 CFR § 184.1193
Trace element solution	
Copper sulfate	21 CFR § 184.1261
Sodium molybdate	Similar to GRN 384 (FDA no questions letter) (see GRN 553, 2014)
Zinc sulfate	21 CFR § 182.8997
Cobalt (II) chloride	--
Manganese chloride	21 CFR § 184.1446

Ingredient	CFR Citation
Nickel sulfate	21 CFR § 184.1537
Vitamins	
Vitamin B12	21 CFR § 184.1945
Biotin	21 CFR § 182.8159
Thiamine hydrochloride	21 CFR § 184.1875
Processing aids	
Sodium hydroxide solution	21 CFR § 184.1763
Ammonium hydroxide solution	21 CFR § 184.1139
Defoaming agents	21 CFR § 173.340
Feeding medium	
Dextrose syrup	21 CFR § 184.1865

Once fermentation is complete (i.e., as determined by carbon usage, cell growth, oil synthesis activity, oil content, and oil fatty acid profile), the crude oil that accumulates intracellularly is recovered from the fermentation broth via an aqueous extraction process. To release the oil from the cells, the cell wall must be disrupted. In the cell-wall disruption process, the fermentation broth is pH-adjusted with sodium hydroxide and hydrolyzed enzymatically. As a result, no intact algae remain in the oil. The oil is then recovered from the hydrolyzed biomass. In the oil recovery process, the hydrolyzed biomass can be treated and centrifuged to yield the crude algal oil. At each step after cell-wall disruption, exposure to air is minimized. Antioxidants can be added as necessary. The manufacturing process is represented schematically in Figure 3 and is essentially the same as that described for the production of the currently authorized oil from *Schizochytrium* sp. (DHA-B) (FDA, 2014a). Figure 4 presents the subsequent DHA-algal oil refining process.

An additional optional step that may be employed prior to refining, or after bleaching, is fractionation/winterization, in which the oil is cooled and centrifuged or filtered to obtain a crude algal oil that flows easily at room temperature. Process conditions of the other steps shown in the above flow diagram do not change. Optional steps described below are customer-driven and conducted at a customer's request. The steps in the algal oil refining process are described in more detail in the sections that follow.

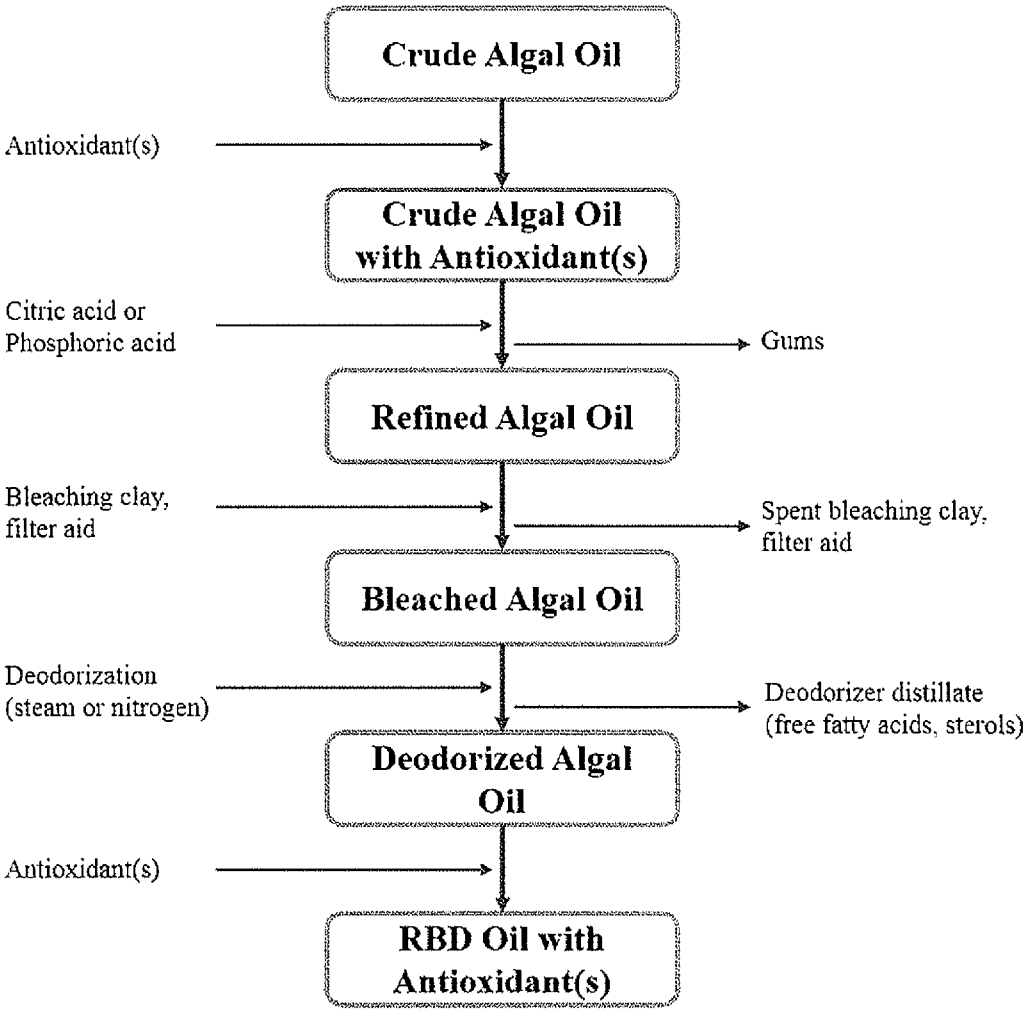

Figure 4. DHA algal oil refining process

Degumming/Alkali Refining (Optional)

Most crude oils isolated from natural sources contain gums and free fatty acids. Gums, after separation from the oil, consist primarily of phospholipids, some entrained oil, traces of soluble sugars, and solid particles. Some of the phospholipids become hydrated and oil insoluble. Hydrating the gums and removing the hydrated gums from the oil prevents the formation of gum deposits in downstream processes. Water degumming is used to remove phosphatides and water-soluble components from the oil. Analysis of the crude algal oil has shown that almost all of the fatty acids are in the form of triglycerides, and very little in the form of phospholipids or free fatty acids, thus making the degumming and/or alkali refining steps not essential. If the degumming step is skipped, the small amounts of phospholipids present can be removed in the subsequent bleaching step.

If a degumming step is desired, a water degumming process is employed. Crude algal oil is treated with 250–2000 ppm of phosphoric acid or citric acid at 60–90°C with vigorous

stirring, and then gently stirred for a period of 10–90 minutes. Water (1–5% [w/w]) is added at 60–70 °C and stirred vigorously. The oil is then stirred gently for 15–60 minutes to aid in hydrating the phospholipids present. An aqueous phase is formed that consists of an emulsion of hydrated phospholipids and entrained oil. The phases are separated from each other by settling and filtration, or by centrifugation, yielding a stream of acid-degummed oil and a stream of wet gums.

If an alkali refining step is required, the algal oil is treated with an alkali solution to convert the free fatty acids into soaps, which are readily separated from the oil. After alkali refining, the oil is water-washed to remove the residual soap.

Bleaching

Following degumming, bleaching of the algal oil is the step in the refining process that removes impurities that degrade the appearance, stability, and flavor of the oil. As depicted in Figure 3, the bleaching step is preceded by the degumming and neutralization process and removes specific contaminants that are not effectively removed during degumming. Bleaching effectively removes some of the color, residual soaps and gums, trace metals, and oxidation products. It also has an indirect impact on the color of the deodorized oil.

The efficiency of bleaching is affected by moisture level, temperature, contact time, vacuum, oil quality, amount and characteristics of the adsorbent, and the type of equipment employed. The bleaching process can be a batch or continuous type of process. The latter can be either a co-current or a counter-current process. The amount of bleaching clay added depends on the specifications of the bleached oil, such as the residual phosphorus content, fatty acid content, and low soap content. For bleaching the algal oil, about 0.5–5% bleaching clay is used. Typically, the oil is vacuum-dried prior to bleaching, and has a moisture content of <0.5%. The operating temperature is from 90–125°C, and pressure is between 50 to 125 mm Hg (absolute). The total time the bleaching clay is in contact with the oil typically ranges from 15 minutes to 1 hour. The clay is then separated from the oil by filtration, often with the help of a filter aid, such as diatomaceous earth.

Deodorization

The main purpose of deodorization is to remove compounds that cause off-flavors, but the process also removes free fatty acids, tocopherols, squalene, and sterols. In addition, other volatile contaminants that have undesired off-flavors are removed. The oil undergoes heat bleaching, where thermal destruction of flavor precursors and certain colored pigments, such as carotenoids, occurs. The oil becomes lighter in color. Deodorization is performed under vacuum to aid in stripping specific compounds and it protects the oil from oxidation. Although nitrogen can be used as the stripping agent, superheated steam is frequently used.

The deodorization process is fully defined by temperature, time, pressure, and amount of stripping steam. Deodorization on a commercial scale is a multi-step process comprising de-aeration, multi-stage heating, deodorization-de-acidification, and multi-stage cooling of the oil. The oil after bleaching is de-aerated prior to being heated to deodorizing temperatures, to avoid oxidation and polymerization. De-aeration can be accomplished in

a separate vessel connected to the vacuum system (around 50 mbar), or at an even lower pressure in the deodorizer. Sparge steam may be used to improve de-aeration.

Deodorization can be performed in a batch deodorizer, a semi-continuous system, or a continuous system. Stripping efficiency is superior in the continuous system, which has a column filled with structured packing with a high surface area. Counter-current contact of oil with the stripping steam over the structured packing provides efficient stripping with a short contact time. Various configurations of deodorizers can be used (horizontal or vertical vessels, tray-type, or packed columns). Antioxidants such as mixed tocopherols, ascorbyl palmitate, or other safe and suitable antioxidants are again added, as necessary. In addition, non-genetically modified organism (GMO) sunflower or rapeseed oil can be added as an option in order to standardize the oil for DHA content.

Reagents/processing aids that are employed in the extraction and refining process are listed in Table 2. The DHA-rich algal oil is manufactured in accordance with Hazard Analysis Critical Control Point (HACCP) and cGMP, including quality control (QC) checks at every stage of the production process. All the steps outlined in the above manufacturing process are conducted under conditions that minimize the risk of contamination by foreign materials.

Table 2. Reagents/processing aids

Reagent/Processing Aid	CAS Number	CFR Citation
Phosphoric acid	7664-38-2	21 CFR § 182.1073
Citric acid	77-92-9	21 CFR § 184.1033
Clay (bleaching)	68515-07-1	21 CFR § 184.1155
Nitrogen	7727-37-9	21 CFR § 184.1540
Mixed tocopherols	1406-18-4	21 CFR § 182.3890; 21 CFR § 182.8890
Ascorbyl palmitate (optional)	137-66-6	21 CFR § 182.3149
Alcalase*	9014-01-1	21 CFR § 184.1027
Sodium hydroxide	130-73-2	21 CFR § 184.1763
Sodium sulfate	7757-82-6	21 CFR § 186.1797
Filter aid	68855-54-9	21 CFR § 182.90
Rapeseed oil	8002-13-9	21 CFR § 184.1555
High-oleic sunflower oil	8001-21-6	GRAS per 21 CFR § 170.30
Rosemary extract (optional)	84604-14-8	GRAS per 21 CFR § 182.20

*Protease preparation produced by *Bacillus lichenformis*; a safe and suitable food-grade enzyme that complies with FAO/WHO JECFA and Food Chemicals Codex (FCC) specifications for food-grade enzymes

Product Specifications

The specifications for DHA-rich oil from *Schizochytrium* sp. G3 manufactured by the process outlined above are found in Table 3 and are identical to those for the subject of GRN 677, DHA-rich oil from *Schizochytrium* sp. T18. Analytical results for three non-consecutive lots of this *Schizochytrium* sp. G3 manufactured Mara DHA-algal oil can be found in Table 4. The proximate analysis of this DHA-algal oil is presented in Table 5.

Table 3. Specifications for DHA-algal oil from *Schizochytrium sp.* G3

Parameter	G3 DHA Oil Specification	Mara GRN 677 Specification (T18)	Test Method
Acid value (mg KOH/g)	Max 0.5	Max 0.5	AOCS Cd 3d-63
Peroxide value (meq/kg)	Max 5.0	Max 5.0	AOCS Cd 8-53

Moisture & Volatiles (%)	Max 0.05	Max 0.05	AOCS Ca 2c-25
Unsaponifiable matter (%)	Max 3.5	Max 3.5	AOCS Ca 6a-40
Trans-Fatty acids (%)	Max 2.0	Max 2.0	AOCS 2a-94
DHA (% Area)	Min 35	Min 35	AOCS Ce 1b-89, mod.
Arsenic (mg/kg)	<0.1	<0.1	AOAC 2013.06
Copper (mg/kg)	<0.1	<0.1	AOCS Ca 17-01
Iron (mg/kg)	<0.2	<0.2	AOCS Ca 17-01
Mercury (mg/kg)	<0.1	<0.1	AOAC 2013.06
Lead (mg/kg)	<0.1	<0.1	AOAC 2013.06

Table 4. Analytical results for three non-consecutive lots of Mara DHA-algal oil produced using *Schizochytrium* sp. G3 compared to FCC specifications and a representative lot of GRN 677 Mara DHA-algal oil

Parameter	G3 DHA Algal Oil	DHA Algal Oil	Mara GRN 677	G3 DHA Algal Oil	G3 DHA Algal Oil	G3 DHA Algal Oil
Sample Number	**Specifications**	**FCC Spec (2019)**	**N-2-010-C**	**N-2-022-R**	**N-2-024-R**	**N-2-026-R**
Acid value (mg KOH/g)	≤0.5	NA	0.06	0.12	0.11	0.14
Peroxide value (meq O^2/kg)	≤5.0	≤ 5.0	<0.1	0.37	0.52	0.41
Unsaponifiable matter (weight %)	≤3.5	≤ 4.5	2.50	0.56	0.59	0.69
Moisture (%)	≤0.05	NA	<0.05	<0.01	<0.01	<0.01
DHA (area %)	≥35	30-40	39.6	54.0	52.3	57.4
Trans fatty acids (area-%)	≤2.0	NA	<0.05	<0.05	<0.05	<0.05
Iron (mg/kg)	< 0.2	NA	<0.020	<0.020	0.036	<0.020
Copper (mg/kg)	< 0.1	NA	0.03	<0.01	<0.01	<0.01
Arsenic (mg/kg)	< 0.1	≤ 0.1	<0.01	<0.02	<0.02	<0.02
Mercury (mg/kg)	<0.1	≤ 0.1	<0.01	<0.01	<0.01	<0.01
Lead (mg/kg)	<0.1	≤ 0.1	<0.01	<0.02	<0.02	<0.02
Free fatty acids (% as oleic acid)	NA	≤ 0.4	NA	0.06	0.06	0.07
Total oxidation value	NA	≤ 26.0	NA	<1.74	2.24	<1.82
Anisidine value	NA	≤ 20.0	NA	<1.0	1.2	<1.0

Table 5. Proximate analysis of three non-consecutive lots of Mara DHA-algal oil produced using *Schizochytrium* sp. G3

Parameter	Lot No.		
	N-2-022-R	N-2-024-R	N-2-026-R
Moisture (g/100g)	<0.30	<0.30	<0.30
Ash (g/100g)	<0.1	<0.1	<0.1
Protein (g/100g)	<0.20	<0.20	<0.20
Fat (Acid Hydrolysis) (g/100g)	101	102	101
Carbohydrate (g/100g)	<0.1	<0.1	<0.1

As seen in Table 6, the fatty acid profile of this *Schizochytrium* sp. G3 manufactured Mara DHA-algal oil is consistent across lots. All of the fatty acids detected are well-known components of the human diet and found in both animal and vegetable food sources. The major fatty acids are DHA, myristic acid, palmitic acid, and docosapentaenoic acid. As presented in Table 4, this *Schizochytrium* sp. G3 manufactured Mara DHA algal oil is comparable to that of several other DHA-algal oils, including the DHA-algal oil that was the subject of GRN 677. When compared to the spectrum of available DHA oils from a variety of sources, including algae and fish, the fatty acid profile of this specific DHA algal oil is comparable to currently marketed DHA oil products. The analyzed lots of this Mara DHA-algal oil are consistent with those lots submitted previously to the UK Food Standard Agency (ONC, 2011). Furthermore, a slight variation in the fatty acid content of dihomo gammalinolenic acid, arachidonic acid, eicosapentaenoic acid (EPA), docosapentaenoic acid (DPA), and DHA, compared to FCC specifications, has no appreciable effect on the quality or safety of the proposed DHA-algal oil for use in food. Certificates of Analysis (COA) for the proposed DHA-algal oil can be found in Appendix A.

The sterol content of this specific DHA-algal oil was also determined (see Table 7). The detected sterols and stanols are also present in the human diet from vegetable and animal food sources such as common edible oils. Additionally, the sterol profile of this DHA-algal oil is similar to that found in other algal oils and fish oils that are currently used in food, including infant formula (FDA, 2001, 2014a). The major sterols found in the DHA-algal oil are found in human breast milk and commercially available infant formula (Mellies et al., 1976, FDA, 2014a).

Table 6. Fatty acid profile (area %) of three non-consecutive lots of Mara DHA-algal oil produced using *Schizochytrium* sp. G3

Parameter		Lot No.		
		N-2-022-R	N-2-024-R	N-2-026-R
10:0	Capric acid	0.1	0.1	0.1
12:0	Lauric acid	0.1	0.1	0.1
14:0	Myristic acid	3.3	2.7	2.6
14:1	Myristoleic acid	<0.1	<0.1	<0.1
15:0	Pentadecanoic acid	0.2	0.3	0.2
16:0	Palmitic acid	26.1	26.5	21.6
16:1 (n-7)	Palmitoleic acid	0.3	0.2	0.3
16:4 (n-1)	Hexadecanoic acid	1.5	2.2	2.0
17:0	Heptadecanoic acid	0.1	0.1	0.1
17:1 (n-8)	Margaroleic acid	0.2	0.3	0.2
18:0	Stearic acid	0.7	0.9	0.6
18:1 (n-5)	Octadecenoic acid	0.2	0.4	0.4
18:1 (n-7)	Vaccenic acid, cis	0.3	0.5	0.2
18:1 (n-9)	Oleic acid, cis	0.3	0.3	0.3
18:2 (n-6)	Linoleic acid	<0.1	<0.1	<0.1
18:3 (n-3)	Alpha-linolenic acid	0.1	0.2	0.1
18:4 (n-3)	Steridonic acid	0.1	0.2	0.2
20:0	Arachidic acid	0.2	0.1	0.1
20:1	Eicosenoic acid	<0.3	<0.3	<0.3
20:3 (n-6)	Dihomo gammalinolenic acid	0.1	0.1	0.1
20:4 (n-3)	Eicosatetraenoic acid	0.6	0.6	0.6
20:4 (n-6)	Arachidonic acid	0.1	0.1	0.1
20:5 (n-3)	Eicosapentaenoic acid (EPA)	0.5	0.5	0.5
22:0	Behenic acid	0.1	0.1	0.1
22:1 (n-7)	15-Docosenoic acid	1.1	0.5	1.0
22:5 (n-3)	Docosapentaenoic acid (DPA)	0.1	0.1	0.1
22:5 (n-6)	Docosapentaenoic acid (DPA)	7.7	9.0	9.2
22:6 (n-3)	Docosahexaenoic acid (DHA)	54.0	52.3	57.4
24:0	Lignoceric acid	<0.1	<0.1	<0.1
24:1 (n-9)	Nervonic acid	0.2	0.1	0.2

Table 7. Sterol content (% total sterols) of three non-consecutive lots of Mara DHA-algal oil produced using *Schizochytrium* sp. G3

Parameter	Lot No.		
	N-2-022-R	N-2-024-R	N-2-026-R
Cholesterol	55.47	50.35	48.27
Brassicasterol	0.59	1.16	1.23
Campesterol	<0.01	<0.01	0.29
Campestanol	<0.01	<0.01	<0.01
Stigmasterol	9.79	11.31	10.45
Delta-7-campesterol	5.81	7.00	8.17
Delta-5,23-stigmastadienol	<0.01	<0.01	<0.01
Clerosterol	19.41	19.30	23.46
Beta-sitosterol	3.58	4.22	3.49
Sitostanol	0.40	0.38	0.31
Delta-5-avenasterol	0.30	0.24	0.27
Delta-5,24-stigmastadienol	3.10	3.72	2.69
Delta-7-stigmastenol	0.92	1.36	0.92
Delta-7-avenasterol	0.20	0.44	0.16
24-Methylene-cholesterol	0.45	0.51	0.29
Total Sterol (mg/kg fat)	2850	2760	2430

It should be noted that numerous other analyses of this specific DHA-algal oil product have been conducted but are not included in the product specifications (e.g., chromium, iron, manganese, molybdenum, nickel, phosphorus, silicon, sulfur, pesticides, mycotoxins, benzo(a)pyrene, polycyclic aromatic hydrocarbons [PAHs}, polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, and dioxin-like polychlorinated biphenyls [PCBs]). While some of these contaminants would not be expected to be present in the DHA algal oil, they are included in the COAs found in Appendix A, and selected results are summarized in Table 8 below. In summary, the analytical results confirm that this finished DHA-algal oil product meets the analytical specifications and confirms the lack of impurities/contaminants of toxicological concern.

Table 8. Select analytical results for residual contaminants*

Lot Number	N-2-022-R	N-2-024-R	N-2-026-R
Elemental Analysis			
Chromium (ppm)	<0.1	<0.1	<0.1
Iron (ppm)	<0.020	0.036	<0.020
Manganese (ppm)	<0.1	<0.1	<0.1
Molybdenum (ppm)	<0.02	<0.02	<0.02
Nickel (ppm)	<0.1	<0.1	<0.1
Phosphorus (ppm)	<1.0	<1.0	<1.0
Silicon (ppm)	<1.0	1.2	<1.0
Sulfur (ppm)	5.2	5.8	5.1
Microbiological Analyses			
Salmonella (/25g)	Not Detected	Not Detected	Not Detected
Escherichia coli (MPN/g)	<3	<3	<3
Staphylococci aureus (CFU/g)	<10	<10	<10
Yeast (CFU/g)	<10	<10	<10
Mold (CFU/g)	<10	<10	<10
Coliforms (CFU/g)	<3	<3	<3
Other Residuals			
Benzo(a)pyrene (ppb)	<5	<5	<5
Polychlorinated Biphenyls (ppm)	<0.02	<0.02	<0.02
PAH 4 (ppb)	<10	<10	<10

*3 non-consecutive lots of Mara DHA-algal oil produced using *Schizochytrium* sp. G3

Toxin production by G3 is unlikely, because there are no reports of toxin production by any of the *Thraustochytriacea*, the family of which *Schizochytrium* is a member. Nevertheless, samples of G3 oil and the biomass (freeze-dried) from which it is obtained have been screened for the following algal toxins (Table 9).

Table 9. Algal toxin analysis*

Toxin	Lot No.**			
	Biomass	**N-2-022-R, Oil**	**N-2-024-R, Oil**	**N-2-026-R, Oil**
Azaspiracids (µg AZA eq/kg)	<30	<30	<30	<30
Pectenotoxins (µg PTX eq/kg)	<30	<30	<30	<30
Yessotoxins (mg YTX eq/kg)	<0.10	<0.10	<0.10	<0.10
Okadaic acid (µg OA eq/kg)	<30	<30	<30	<30
Domoic acid (µg/g)	<3.0	<3.0	<3.0	<3.0
Diarrhetic shellfish toxins (µg OA eq/kg)	<30	<30	<30	<30

*3 non-consecutive lots of Mara DHA-algal oil produced using *Schizochytrium* sp. G3

**Below the Limit of Detection

Stability Data

Stability testing (accelerated conditions) was conducted on three non-consecutive batches of DHA algal oil, as presented in Table 10. DHA algal oil is typically shipped and stored at 4°C, –4°C, or frozen (–25°C). The results of the accelerated stability study demonstrate the stability of the product over an 8-week period. Additional stability testing for a period of 12 months is currently in progress.

Table 10. Accelerated stability study of Mara DHA-algal oil produced using *Schizochytrium* sp. G3

	Specification	Time				
		Initial	Week 4 at 35°C; (55-60%)	Week 8 at 35°C; (55-60%)	Month 1 Frozen (–18°C)	Month 1 Ambient (22–25°C)
Batch No. N-2-022-R						
DHA (%)	Min 35	55.7	55.4	55.8	55.4	55.6
Peroxide Value (meq/kg)	Max 5.0	0.4	0.9	1.1	0.4	2.5
p-Anisidine Value	NA	0.6	1.9	3.2	1.6	1.7
Acid Value (mg KOH/g)	Max 0.5	0.11	0.12	0.10	0.07	0.10
Batch No. N-2-024-R						
DHA (%)	Min 35	54.5	54.1	54.6	54.4	54.3
Peroxide Value (meq/kg)	Max 5.0	0.7	1.7	1.2	1.3	3.4
p-Anisidine Value	NA	1.1	2.4	3.1	1.5	3.0
Acid Value (mg KOH/g)	Max 0.5	0.06	0.10	0.09	0.08	0.09
Batch No. N-2-026-R						
DHA (%)	Min 35	59.5	59.2	59.6	59.4	59.5
Peroxide Value (meq/kg)	Max 5.0	0.6	1.7	1.8	1.0	2.8
p-Anisidine Value	NA	0.6	1.5	2.8	1.4	2.4
Acid Value (mg KOH/g)	Max 0.5	0.08	0.09	0.10	0.09	0.09

§ 170.235 Part 3, Dietary Exposure

The proposed DHA algal oil produced using *Schizochytrium* sp. G3 is intended for use as a direct food ingredient in foods, to increase the dietary intake of the omega-3 fatty acid DHA. The approved use levels for menhaden fish oil (containing both DHA and EPA) in food is outlined in Table 11, as defined in 21 CFR § 184.1472, along with the proposed maximum use levels for the proposed DHA-algal oil.

As noted for menhaden oil and other sources of DHA and/or EPA, FDA has determined that these oils may be used at a level that provides a total intake of DHA and/or EPA up to 3.0 grams per day. A review of previous GRAS notifications indicates that suppliers of DHA and EPA products, as well as their GRAS expert panels, have generally recommended a maximum limit of 1.5 grams of DHA or EPA per day when combined together. The maximum levels of use were designed to ensure that the combined daily intake of the two fatty acid components (i.e., EPA and DHA) would not exceed 3 grams per person per day. FDA has concurred with such an approach, providing "no questions" letters regarding such proposed food uses and associated intakes. In addition, the proposed food uses for this Mara DHA-rich algal oil product are identical to the uses for other GRAS DHA and/or EPA products.

Therefore, in the event that a manufacturer blends this Mara DHA-rich algal oil with another oil that is a source of DHA and/or EPA, such a mixture would be appropriate (in meeting FDA's 3.0-gram-per-day limit as described above), provided that (1) the DHA-rich algal oil is used at a level that would not result in an exposure of more than 1.5 grams of DHA per 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 grams per person per day. Because the proposed DHA algal oil contains approximately 50% DHA, compared to about 20% combined DHA and EPA in menhaden oil, the use levels need to be reduced to 20% of the menhaden oil levels to account for the 50% use level for DHA only, and the difference in concentration of DHA in the proposed algal oil (approximately 50%) compared to the concentration of EPA and DHA in menhaden oil (20%). In summary, the use levels of this Mara DHA-algal oil will be adjusted as necessary to provide no more than 1.5 g DHA per person per day for the food categories listed in 21 CFR 184.1472 (menhaden oil).

The European Union (EU) has also recently amended the levels and conditions of use of the oil from the microalgae *Schizochitrium* sp. (Regulation (EU) 2018/1032). The Annex of the amendment described specified food categories and maximum use levels (mg/100 g for food, and mg DHA/day for dietary supplements) and is included here for reference (EU, 2018).

Table 11. Approved use levels of menhaden oil (DHA+EPA) compared to proposed maximum use levels of Mara's DHA-algal oil* in food

Category of food	Maximum Approved Level of Menhaden Oil in Food (as served)[1]	Maximum Intended Use Level of DHA Algal Oil in Food (as served)[2]
Baked goods, baking mixes	5.0%	1.00%
Cereals	4.0%	0.80%
Cheese products	5.0%	1.00%
Chewing gum	3.0%	0.60%
Condiments	5.0%	1.00%
Confections	5.0%	1.00%
Dairy product analogs	5.0%	1.00%
Egg products	5.0%	1.00%
Fats, oils	12.0%	2.40%
Fish products[3]	5.0%	1.00%
Frozen dairy desserts	5.0%	1.00%
Gelatins, puddings	1.0%	0.20%
Gravies, sauces	5.0%	1.00%
Hard candy	10.0%	2.00%
Jams, jellies	7.0%	1.40%
Meat products	5.0%	1.00%
Milk products	5.0%	1.00%
Nonalcoholic beverages	0.5%	0.10%
Nut products	5.0%	1.00%
Pastas	2.0%	0.40%
Plant protein products	5.0%	1.00%
Poultry products	3.0%	0.60%
Processed fruit juices	1.0%	0.20%

Category of food	Maximum Approved Level of Menhaden Oil in Food (as served)[1]	Maximum Intended Use Level of DHA Algal Oil in Food (as served)[2]
Processed vegetable juices	1.0%	0.20%
Snack foods	5.0%	1.00%
Soft candy	4.0%	0.80%
Soup mixes	3.0%	0.60%
Sugar substitutes	10.0%	2.00%
Sweet sauces, toppings, syrups	5.0%	1.00%
White granulated sugar	4.0%	0.80%

[1] Per 21 CFR § 184.1472
[2] Use levels reduced to 20% (DHA algal oil) of menhaden oil levels, as described above.
[3] While unlikely, it is possible that the DHA algal oil could be used in fish products of the order Siluroformes.
* Mara DHA-algal oil produced using *Schizochytrium* sp. G3

§ 170.240 Part 4, Self-Limiting Levels of Use

The use of DHA and DHA-algal oil and powder in foods is controlled as described in Part 3. Therefore, there are no self-limiting levels of use.

§ 170.245 Part 5, Experience Based on Common Use in Food

The statutory basis for our conclusion of GRAS status in the notice is not based on common use in food.

§ 170.250 Part 6, GRAS Narrative

History of Use/Regulatory Approval of DHA-Algal Oil

DHA-rich oils from numerous sources including microalgae are considered GRAS for use in food for human consumption, including infant formula (FDA, 2001, 2004, 2006, 2010, 2011a,b, 2014a,b, 2017, 2018a–d, 2019a–c). One other GRAS notification (GRN 862) for DHA-rich oil from microalgae is pending (FDA, 2019d). Sources of the oils include *Schizochytrium* sp., *Ulkenia* sp. SAM2179, *Chlorella protothecoides* strain S106, and *Prototheca moriformis* strain S2532. In addition, FDA has approved other sources of DHA for use in human food and/or infant formula, such as menhaden and fish oils (FDA, 2008a). Table 12 lists a number of approvals for DHA from algal sources, as well as marine sources, for incorporation in food and infant formula.

Table 12. Regulatory approvals for use of DHA in food and infant formula

Year Approved	Country	Submission
2001	USA	GRN 41; DHASCO (docosahexaenoic acid-rich single-cell oil) from *Crypthecodinium cohnii* for use in infant formula
2006	USA	GRN 94; Docosahexaenoic acid-rich oil from tuna (DHA-rich tuna oil)
2004	USA	GRN 137; Algal oil (*Schizochytrium* sp.)
2011	USA	GRN 379; DHA from tuna oil
2015	EU/UK	DHASCO-B (docosahexaenoic acid-rich single-cell oil) from *Schizochytrium* sp. for use in infant formula
2015	USA	GRN 553; Algal oil (40% docosahexaenoic acid) derived from *Schizochytrium* sp.
2017	USA	GRN 677; Algal oil (40% docosahexaenoic acid) derived from *Schizochytrium* sp.
2018	USA	GRN 731; Docosahexaenoic acid oil produced in *Schizochytrium* sp.
2018	USA	GRN 732; Docosahexaenoic acid oil produced in *Schizochytrium* sp.
2018	USA	GRN 776; Algal oil (35% docosahexaenoic acid) from *Schizochytrium* sp. FCC-1324
2018	USA	GRN 777; Algal oil (55% docosahexaenoic acid) from *Schizochytrium* sp. FCC-3204

Year Approved	Country	Submission
2019	USA	GRN 836; Algal oil (50-60% docosahexaenoic acid) from *Schizochytrium* sp. HS01
2019	USA	GRN 843; Algal oil (35% docosahexaenoic acid) from *Schizochytrium* sp. strain FCC-1324
2019	USA	GRN 844; Algal oil (55% docosahexaenoic acid) from *Schizochytrium* sp. strain FCC-3204
2018	EU	Oil from micro algae *Schizochytrium* sp. as a novel ingredient in food, including infant formula

As summarized above, DHA produced via fermentation employing various microalgae has been approved previously and sold for incorporation in food and infant formula. This includes approval of algal oil from *Schizochytrium* sp. produced by Mara (i.e., GRN 677; FDA, 2017; EU, 2018).

In addition, DHA-rich oils from microalgal sources that include *Schizochytrium* sp. have been the subject of several authorization decisions and/or notifications under the European Union (EU) Novel Foods and Food Ingredients Regulation 258/97. The first such authorization was Commission Decision 2003/427/EC in June of 2003, which authorized the use of DHA-S oil from the thraustochytrid microalgae *Schizochytrium* sp. in a range of foodstuffs and established a specification for the material (OmegaTech, 2001). This was followed in December 2003 by a notification under Article 5 of the novel food regulation for placement on the market of a DHA-rich oil derived from a second thraustochytrid microalgae, *Ulkenia* sp., on the grounds of its substantial equivalence with the oil from *Schizochytrium* sp. (Schmitt et al., 2012a). To date, algal oil produced from *Schizochytrium* sp. (DHA-S) has been approved for direct use in foods by the U.S. Food and Drug Administration (FDA), Health Canada, European Union, Food Standards Agency of Australia, China's Ministry of Health, and Brazil's National Health Surveillance Agency (FDA, 2014a). Furthermore, a Novel Food Application was approved for the use of DHA-B in conventional foods, infant formula and follow-up formula, and food supplements (DSM, 2013; EU, 2015). In 2009, Commission Decisions 2009/777/EC and 2009/778/EC authorized extensions to the approved food uses of the oils from *Ulkenia* sp. and *Schizochytrium* sp., respectively. A third DHA-rich oil derived from the microalgae *Crypthecodinium cohnii* was already on the EU market before the Novel Food Regulation came into effect and was therefore legally in use without the need for explicit approval (Schmitt et al., 2012a). It should also be noted that, in 2012, the UK Food Standards Agency concluded that T18 algal oil (the subject of GRN 677) met the criteria for equivalence as defined in Article 3(4) of regulation (EC) 258/97, and that the *Schizochytrium* strain used in the production of T18 oil was substantially equivalent to other *Schizochytrium* sp. DHA-rich algal oils (Food Standards Agency, 2012). In 2018, Commission Decision 2018/1032 authorized the extension of the use of the oil from microalgae *Schizochytrium* sp. (EU, 2018). In the U.S., the three DHA-rich oils described

above have also been the subject of GRAS Notifications (GRN Nos. 41, 137, 319) to which the FDA had no objections (FDA, 2001, 2004, 2010).

Safety

DHA is an important component of most cell membranes and tissues. DHA and DHA algal oils are currently marketed for use in food, dietary supplements, and infant formula for human consumption. The Mara DHA algal oil from *Schizochytrium* sp. G3 has a lipid (fatty acid) profile similar to that of currently marketed DHA from *Schizochytrium* sp., including T18 (GRN 677; FDA, 2017). Regulatory authorities have reviewed the safety of DHA and DHA-algal oils and found their use to be safe in human food, including infant formula. Numerous studies and publications support the safety of DHA and DHA-algal oils, including *in vitro* studies, *in vivo* animal studies, and clinical studies in humans. The most relevant studies on DHA including acute and subchronic toxicity, reproductive and developmental toxicity, mutagenicity and genotoxicity, chronic toxicity, and irritation/sensitization, along with clinical and epidemiological studies, all were summarized and reviewed as part of Mara's GRN 677 Notification for DHA algal oil from *Schizochytrium* sp. T18, as well as the other GRNs listed in Table 12. Kroes et al. (2003) reviewed and summarized the well understood metabolic fate of dietary DHA, which is similar to other dietary fatty acids. The published data, as well as reviews conducted by regulatory authorities, support the conclusion that Mara's DHA-rich algal oil produced using *Schizochytrium* sp. G3 is safe for use in food.

A new literature search was performed to identify available safety data on DHA and DHA algal oil through December 2019. This included searching sources of information such as publicly available assessments, databases, or reviews from organizations, including the European Food Safety Authority (EFSA), Joint FAO/WHO Expert Committee on Food Additives (JECFA), U.S. FDA, and the World Health Organization (WHO), general internet searching, and searching databases such as Embase, Medline, Toxline, and PubMed. The most recent published literature on DHA and DHA algal oil consisted primarily of reviews of clinical trials and the efficacy of DHA in preventing certain health outcomes. Pivotal safety studies conducted by with algal oil from *Schizochytrium* sp. T18 are summarized below and support the safety Mara of the algal oil from *Schizochytrium* sp. G3.

Toxicological Studies

Animal Studies (with Mara Schizochytrium sp. T18-derived algal oil)

Toxicity testing has been conducted with a DHA-rich algal oil product from *Schizochytrium* sp. T18 (Schmitt et al., 2012a,b), which is considered essentially equivalent to that of *Schizochytrium* sp. G3. The animal studies conducted with Ocean Nutrition's (now Mara) T18 algal oil and included in GRN 677 are summarized below. Schmitt et al. (2012a) conducted a battery of *in vitro* and *in vivo* genotoxicity tests (microbial reverse mutation assay, *in vivo* rat bone marrow micronucleus assay, and chromosomal aberration assay in cultured human peripheral blood lymphocytes) with DHA-rich algal oil T18. The DHA-rich algal oil was not mutagenic or genotoxic in any of the assays. In addition, the acute oral LD_{50} in rats was estimated to be greater than 5000 mg/kg of body weight.

In addition, Schmitt et al. (2012a) administered DHA-rich algal oil at concentrations of 0, 10,000, 25,000, or 50,000 ppm in the diet to rats for 13 weeks. The algal oil was well-tolerated, and there was an absence of toxicologically significant treatment-related effects on the general condition and appearance of the rats, neurobehavioral endpoints, growth, feed and water intake, ophthalmoscopic examinations, routine hematology and clinical chemistry parameters, urinalysis, and necropsy findings. The no-observed-adverse-effect level (NOAEL) was the highest dietary concentration level of 50,000 ppm, equivalent to 3,305 and 3,679 mg/kg bw/day for male and female rats, respectively. The study results confirmed that the DHA-rich algal oil T18 possessed a toxicity profile similar to other currently marketed algal oils and supported the safety of the proposed DHA-rich algal oil T18 for its proposed use in food.

Schmitt et al. (2012b) conducted both a developmental toxicity study and a 3-month dietary toxicity study with an *in utero* exposure phase of T18 in the rat. Based on the absence of maternal and developmental toxicity at any dose level tested in the developmental toxicity study, the high dose of 2000 mg/kg/day was considered the NOAEL for maternal toxicity and embryo/fetal development when this DHA-rich algal oil was administered orally by gavage to pregnant Crl:CD(SD) rats during gestation days 6–19. In the 3-month dietary toxicity study with an *in utero* phase, the NOAELs for systemic toxicity for F_0 male and female rats and F_1 male rats were considered to be 50,000 ppm (highest concentration administered) and 25,000 ppm for F_1 female rats (equivalent to 2,065 mg/kg bw/day, based on higher mean body weight, body-weight gain, and food consumption).

Mean body-weight gain for the 50,000-ppm algal oil group females was similar to the DHA fish oil group during PNDs 21–35. However, slightly higher mean body-weight gain was noted for females in this group beginning on PND 35 and generally continuing throughout the remainder of the study; the difference was significant ($p<0.05$) during PNDs 77–84 only. As a result, mean body-weight gain in the 50,000-ppm algal oil group females was 32 g higher than the DHA-fish oil group when the entire generation (PNDs 21–112) was evaluated, and mean body weight was higher during PNDs 70–112 (significant; $p < 0.05$ on PND 84 only). These increases were attributed to algal oil exposure. Mean food consumption in the 50,000 ppm algal oil group females was generally higher than the DHA- fish oil throughout the entire generation (PND 21–112); the differences were often significant ($p < 0.05$ or $p < 0.01$). These increases corresponded to the effects on mean body weights observed in this group and, therefore, were attributed to test-article exposure.

The 50,000-ppm exposure level was equivalent to 3421 and 2339 mg/kg/day for F_0 males during pre-mating and after mating, respectively; 3558, 3117, and 7464 mg/kg/day for F_0 females during pre-mating, gestation, and lactation, respectively; and 3526 and 4138 mg/kg/day for F_1 males and females, respectively. Reproductive performance values, estrous cycle length, gestation length, process of parturition, and the numbers of former implantation sites and unaccounted-for sites for the F_0 generation were unaffected by algal oil exposure. F_1 generation postnatal survival and developmental parameters were unaffected by algal oil exposure at all dietary concentrations tested. No neurotoxic effects were noted at any algal oil exposure level. The authors concluded that the results further supported the safety of DHA-rich algal oil T18 for its proposed use in food. The above studies are summarized in Table 13.

Table 13. Summary of preclinical toxicological study data on DHA-rich algal oil T18

Findings/Observations	Reference
Acute Toxicity	
Results: DHA-rich algal oil T18; oral LD_{50} in female Sprague-Dawley albino rats only, >5 g/kg.	Schmitt et al., 2012a
Subchronic Toxicity	
Study Design: Male and female Hsd:Sprague-Dawley SD rats were administered 0, 1, 2.5, or 5.0% DHA-rich algal oil T18 in the diet for 13 weeks. **Results:** NOAEL was the highest concentration tested (5% in the diet), equivalent to 3305 and 3679 mg/kg bw/day in male and female rats, respectively.	Schmitt et al., 2012a
Reproductive/Developmental Toxicity	
Study Design: DHA-rich algal oil T18 was tested for reproductive and developmental toxicity in Sprague-Dawley rats following oral gavage administration. **Results (Developmental/Maternal Toxicity):** The DHA-algal oil (dosage levels of 400, 1000, and 2000 mg/kg/day) did not produce maternal and developmental toxicity at any dosage level. The high dosage level tested of 2000 mg/kg/day was considered to be the NOAEL for maternal toxicity and embryo/fetal development when DHA-rich algal oil was administered orally by gavage to pregnant Crl:CD(SD) rats during gestation days 6–19. **Results (Reproductive Toxicity):** In a 3-month dietary toxicity study with an *in utero* exposure phase in rats, the NOAEL for F0 male and female and F1 male systemic toxicity was considered to be 50,000 ppm (highest concentration administered) and 25,000 ppm for F1 female systemic toxicity (based on higher mean body weight, body-weight gain, and food consumption). Reproductive performance values, estrous cycle length, gestation length, or the process of parturition, and the numbers of former implantation sites and unaccounted-for sites of the F0 generation were unaffected by algal oil exposure. F1 postnatal survival and developmental parameters were unaffected by algal oil exposure at all dietary concentrations. There were no neurotoxic effects noted at any DHA exposure level.	Schmitt et al., 2012b
Genotoxicity/Mutagenicity	
Study Designs: DHA-rich algal oil T18 was tested in a battery of *in vitro* and *in vivo* genotoxicity tests (microbial reverse mutation assays, rat bone marrow micronucleus assay, chromosomal aberration assay in human peripheral blood lymphocytes). **Results:** In all assays, the DHA-algal oil did not demonstrate mutagenic or genotoxic potential.	Schmitt et al., 2012a

Animal Studies (with other DHA algal oil products)

Numerous studies have been conducted with other DHA-algal oils and fish oils, including acute toxicity studies (FDA, 2010), subchronic studies (Arterburn et al. 2000a; Blum et al., 2007a; Boswell et al., 1996; Burns et al., 1999; Fedorova-Dahms et al., 2011; Hammond et al., 2001a; Kroes et al., 2003; Lewis et al., 2016; Wilbert et al., 1997), reproductive and developmental toxicity studies (Arterburn et al. 2000b; Blum et al., 2007b; Falk et al., 2017; Hammond et al., 2001b,c; Kroes et al., 2003), genotoxicity and mutagenicity studies (Arterburn et al., 2000c; Blum et al., 2007a; Fedorova-Dahms et al., 2011; Hammond et al., 2002; Kroes et al., 2003), and other safety-related studies (Abril et al., 2003; Fedorova-Dahms et al., 2014; Huang et al., 2002; Huang et al., 2015; IOM, 2005; Turk et al., 2013). No toxicologically significant treatment-related effects were observed in these studies. In addition, numerous safety studies of a dried algal biomass were conducted (i.e., *in vitro* and *in vivo* genetic toxicity, subchronic toxicity in rats, reproductive and developmental toxicity in rats and/or rabbits), also without notable toxicity (GRN 553; FDA, 2014a).

The FDA has reviewed the safety information submitted as a part of GRNs for these DHA oil products (e.g., DHASCO-B [FDA, 2000, 2014a]; DHA-45 oil [Lonza; FDA, 2010], fish/anchovy oil [FDA, 2003]). As one example, several published studies were submitted as part of GRN 319 (FDA, 2010) for a DHA algal oil derived from *Ulkenia* sp. SAM2179. Based on the entirety of the regulatory and safety information/data provided, FDA issued a "letter of no objection" regarding the proposed use of DHA algal oil (*Ulkenia* sp. SAM 2179) in food. Similar safety studies and resultant FDA "no-questions letters" have also been issued for other DHA sources (e.g., fish oils) and GRAS notifications, as described in the History of Use section (Part 6).

A new literature search was performed to identify available safety data on DHA and DHA algal oil through December 2019. The most recent published literature on DHA and DHA algal oil contain primarily reviews of clinical studies and the efficacy of DHA in preventing certain health outcomes.

Human Studies — Adults

Adverse effects observed in human studies involving very high doses of n-3 fatty acids have included bleeding complications, impaired immune function, increased lipid peroxidation, increased LDL-cholesterol, impaired lipid and glucose metabolism, and gastrointestinal disturbances (EFSA, 2012). However, it was noted that the reported oxidative damage seemed to be associated with very high doses of DHA and EPA, and products that were not supplemented with vitamin E (EFSA, 2012).

Kroes et al. (2003) reviewed clinical studies related to the safety of DHA oils and described numerous clinical trials of 1 week to 1+ years in length. The authors indicated that the clinical trials reported that DHA (at intakes up to 6 g DHA/person/day) in fish or marine-derived oils, alone or in combination with EPA and/or DPA, did not produce adverse effects on identified parameters of interest such as LDL-cholesterol levels, glycemic control, bleeding time, platelet aggregation, and/or other hemostatic parameters.

An EFSA expert panel published a scientific opinion paper on the tolerable upper intake level (UL) of the LCPUFAs, EPA, DHA, and docosapentaenoic acid (DPA) (EFSA, 2012). The EFSA Panel considered the adverse effects in humans described above, following high intakes of DHA and EPA. Long-term intervention studies that evaluated the effects of supplemental intakes of EPA and DHA, either alone or in combination, at doses of up to about 1 g/day on a variety of health outcomes (e.g., cardiovascular, neurological, immunological) were reviewed. The EFSA Panel stated that the clinical studies generally reported no adverse effects related to the consumption of DHA or EPA at these doses (i.e., either alone or in combination, up to about 1 g/day). They also concluded that long-term supplemental intakes of DHA and EPA (combined up to about 5 g/day) do not increase the risk of spontaneous bleeding episodes or bleeding complications, even in subjects at high risk for bleeding (e.g., taking acetylsalicylic acid or anti-coagulants). The Panel (EFSA, 2012) concluded that supplemental intakes of EPA and DHA combined at doses up to 5 g/day, and supplemental intakes of EPA alone up to 1.8 g/day, do not raise safety concerns for the adult population.

As stated previously, FDA has determined that DHA-rich oils can be used at a level that provides a total intake of DHA and/or EPA up to 3.0 grams per day. Numerous clinical trials have been conducted on DHA-rich oils, including algal oils and biomass. The trials have included adults, children, and infants. Overall, the published scientific literature continues to support the safety of EPA/DHA intakes up to 3 grams/day. A review of previous GRAS notifications also indicates that suppliers of DHA and EPA products, as well as their GRAS expert panels, have generally recommended a maximum limit of 1.5 grams of DHA or EPA per day when combined together. The maximum levels of use were designed to ensure that the combined daily intake of the two fatty acid components (i.e., EPA and DHA) would not exceed 3 grams per person per day. FDA has concurred with such an approach, providing "letters of no objection" regarding such proposed food uses and associated intakes.

Numerous scientific and regulatory authorities such as the German Federal Risk Assessment Agency (BfR), Norwegian Scientific Committee for Food Safety (VKM), and the U.S. Institute of Medicine (IOM) have also evaluated the available long-term human intervention studies and published scientific opinions related to possible adverse effects and health outcomes related to consumption of DHA and/or EPA (EFSA, 2012; IOM, 2005), reaching conclusions similar to that of the EFSA review panel (2012). The EFSA panel (2012) considered and referenced all the data/opinions of all these authorities as part of their review.

Safety Data Summary

DHA and DHA-algal oils are currently marketed for use in food, infant formula, and dietary supplements for human consumption. The DHA-algal oil from *Schizochytrium* sp. G3 has a proximate composition and lipid (fatty acid and sterol) profile similar to that of currently approved/marketed DHA oils from *Schizochytrium* sp. and other algal and marine sources, including Mara's *Schizochytrium* sp. T18. Regulatory authorities have reviewed the extensive safety study database of DHA and DHA-rich algal oils and found them to be

safe for use in human food, as well as infant formula. Numerous studies have been conducted and published in support of the safety evaluation of DHA and DHA-algal oils, including *in vitro* studies, *in vivo* animal studies, and clinical studies in humans, including infants. The most relevant studies on DHA including acute and subchronic toxicity, reproductive and developmental toxicity, and mutagenicity and genotoxicity, along with clinical and epidemiological studies, have been reviewed and summarized as part of numerous GRNs, as referenced in Table 12.

In summary, the available published scientific data on the safety of DHA from algae and other sources (e.g., fish oil), including *Schizochytrium* sp. algal sources, are extensive. The compositional profile of the DHA-rich algal oil ingredient presents no obvious safety concerns. The totality of published study data, as presented in previous GRNs reviewed by FDA support the safe use of Mara's DHA algal oil from *Schizochytrium* sp. G3 in foods. Additionally, FDA has already reviewed numerous GRAS notifications for similar products and their use in foods and infant formulas and issued "letters of no objection." In addition, DHA products have been reviewed and approved around the world for addition to food, including infant formula, and for use as a dietary supplement.

Basis for the GRAS Determination

Introduction

The regulatory framework for determining whether a substance can be considered generally recognized as safe (GRAS) in accordance with section 201(s) (21 U.S.C. § 321(s)) of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. § 301 et. Seq.) ("the Act"), is set forth at 21 CFR 170.30, which states:

> General recognition of safety may be based only on the view of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.
>
> General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies, which may be corroborated by unpublished studies and other data and information.

These criteria are applied in the analysis below to determine whether the use of DHA-rich algal oil in foods is GRAS based on scientific procedures. All data used in this GRAS determination are publicly available and generally known, and therefore meet the "general recognition" standard under the FD&C Act.

Safety Determination

DHA and DHA-algal oils are currently marketed for use in food for human consumption, including infant formula, as well as dietary supplements. The proposed DHA-algal oil and encapsulated powder from *Schizochytrium* sp. G3 has a composition and lipid (fatty acid and sterol) profile similar to that of currently approved/marketed DHA oils from Mara's *Schizochytrium* sp. T18 and other algal and marine sources. Regulatory authorities have reviewed the extensive safety study database of DHA and DHA-algal and fish oils and found no issues of concern with respect to their use in human food, including infant formula. Numerous studies have been conducted and published in support of the safety evaluation of DHA and DHA-algal and fish oils, including *in vitro* studies and *in vivo* animal studies (i.e., acute and subchronic toxicity, reproductive and developmental toxicity, mutagenicity and genotoxicity, chronic toxicity, irritation/sensitization), as well as clinical studies in infants and adults.

DHA-rich oils from numerous sources, including microalgae, are considered GRAS for use in food for human consumption, including infant formula (FDA 2001, 2004, 2006, 2010, 2011a,b, 2014a,b, 2017, 2018a–d, 2019a–c). One other GRAS notification (GRN 862) for DHA-rich oil from microalgae is pending (FDA, 2019d). Sources of the DHA-rich algal oils include *Schizochytrium* sp., *Crypthecodinium cohnii*, *Ulkenia* sp. SAM2179, *Chlorella protothecoides* strain S106, and *Prototheca moriformis* strain S2532. In addition, FDA has approved other DHA sources, such as menhaden and fish oils, for use in human food and/or infant formula.

In Europe, DHA-rich oils from microalgal sources have been the subject of several authorization decisions and/or notifications under the EU Novel Food Regulation 258/97. A Novel Food Application was approved for the use of DSM's DHASCO-B from *Schizochytrium* sp. in conventional foods, infant formula and follow-up formula, and food supplements (DSM, 2013; EU, 2015). The first authorized use of DHA-rich oil from the thraustochytrid microalgae *Schizochytrium* sp.was for a range of foodstuffs and they established a specification for the material. The second was for a DHA-rich oil derived from a second thraustochytrid microalgae, *Ulkenia* sp., based on its substantial equivalence with the oil from *Schizochytrium* sp. The other decisions authorized extensions to the approved food uses of the oils from *Ulkenia* sp. and *Schizochytrium* sp., respectively. An additional DHA-rich oil derived from the microalgae *Crypthecodinium cohnii* was already on the EU market before the Novel Food Regulation came into effect and was therefore legally and safely in use without the need for explicit approval. It should also be noted that in 2012 the UK Food Standards Agency concluded that T18 algal oil met the criteria for equivalence to the currently marketed DHA algal oils, as defined in Article 3(4) of regulation (EC) 258/97, and that the *Schizochytrium* strain used in the production of T18 oil was closely related to the organism used in the production of other *Schizochytrium* sp. DHA-rich algal oils (Food Standards Agency, 2012). To date, algal oil produced from *Schizochytrium* sp. has been approved for direct use in foods by the U.S. FDA, Health Canada, European Union, Food Standards Agency of Australia, China's Ministry of Health, and Brazil's National Health Surveillance Agency (FDA, 2014a).

The safety of orally administered DHA from many different sources (e.g., fish oil), including Mara's proposed algal source (*Schizochytrium sp.* G3) and previously submitted *Schizochytrium sp.* T18, been characterized extensively in the publicly available preclinical and clinical study literature. The compositional profile of the proposed DHA-rich algal oil from *Schizochytrium sp.* G3 presents no obvious safety concerns. Finally, similar DHA products have been reviewed and approved around the world for addition to food and infant formula.

General Recognition of the Safety of DHA-Algal Oil

The intended use of a DHA-rich algal oil has been determined to be safe through scientific procedures as set forth in 21 CFR § 170.3(b), thus satisfying the so-called "technical" element of the GRAS determination, and this conclusion is based on the following:

- The DHA product that is the subject of this GRAS determination is an extracted and refined oil from the wild-type heterotrophic microalgae *Schizochytrium* sp. G3. It is a mixture of triglycerides containing mostly PUFA, in which the predominant fatty acid (>35%) is DHA. The DHA manufacturing process starts with fermentation followed by refining of the crude DHA-algal oil isolated from the fermentation process. The DHA-algal oil product is manufactured consistent with cGMP for food (21 CFR Part 110 and Part 117 Subpart B). The raw materials and processing aids used in the manufacturing process are food grade and/or commonly used in fermentation and food manufacturing processes.
- The possible presence of microalgae toxins from *Schizochytrium* sp. has been addressed previously as part of a substantial equivalence submission (ONC, 2011), in GRAS Notification (GRN) No. 553 (FDA, 2014a), and as part of this GRAS notification. Toxin production is unlikely, because there are no known reports of toxin production by thraustochytrids, of which *Schizochytrium* is a member (ONC, 2011; Hammond et al., 2002). In addition, *Schizochytrium* sp. G3 oil and algal biomass were screened for the presence of toxins, including azaspiracids, pectenotoxins, okadaic acid, yessotoxins, and diarrhetic shellfish toxins (DSP), none of which were detected.
- There is common knowledge of a long history of human consumption of DHA from food and foods containing added DHA, from infant formula, and from other products such as dietary supplements. It will be added to food to supplement the dietary intake of the omega-3 fatty acid DHA.
- Literature searches did not identify safety/toxicity concerns related to any individual fatty acid or their ratios in the proposed DHA-algal oil. The *Schizochytrium* sp. G3 produced DHA oil is similar in fatty acid profile to T18 algal oil and other commercially available edible oils incorporated in foods and infant formulas, and to other algal oils and fish oils (e.g., krill oil) that are currently used in food and/or infant formula.

- The proposed uses of the DHA-algal oil product from *Schizochytrium* sp. G3 in food are identical to the approved uses for other GRAS DHA and/or EPA products. As with the use of menhaden oil, the maximum levels of use were designed to ensure that the combined daily intake of the two fatty acid components (i.e., EPA and DHA) would not exceed 3 grams per person per day. In the event that a manufacturer blends Mara's DHA-rich algal oil or powder with another oil that is a source of DHA and/or EPA, such a mixture would meet FDA's daily exposure criteria, provided that (1) the DHA-rich algal oil is used at a level that would not result in an exposure of more than 1.5 grams of DHA per 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 grams per person per day. Because the proposed DHA-algal oil contains approximately 50% DHA, compared to about 20% combined EPA and DHA in menhaden oil, the use levels need to be reduced to 20% (as described in Table 11) of the menhaden oil use levels to account for the 50% percent use level for DHA only, and the difference in concentration of DHA in the proposed algal oil (50%) compared to the concentration of EPA and DHA in menhaden oil (20%).
- DHA-rich oils from numerous sources, including microalgae, are considered GRAS for use in food for human consumption, including infant formula (FDA 2001, 2004, 2006, 2010, 2011a,b, 2014a, b, 2017, 2018a–d, 2019a–c). One other GRAS notification (GRN 862) for DHA-rich oil from microalgae is pending (FDA, 2019d). Sources of the oils include *Schizochytrium* sp., *Ulkenia* sp. SAM2179, *Chlorella protothecoides* strain S106, and *Prototheca moriformis* strain S2532. In addition, FDA has approved other sources of DHA for use in human food and/or infant formula, such as menhaden and fish oils (FDA, 2008a).
- Toxicity testing has been conducted with Mara's DHA-rich algal oil product from *Schizochytrium* sp. T18 (essentially equivalent to DHA from *Schizochytrium* sp. G3) and includes acute and subchronic toxicity studies, a battery of genotoxicity studies, and developmental and reproductive toxicity studies. In all of the studies, no evidence of toxicity was noted at the highest dose levels tested.
- The body of publicly available scientific literature on the consumption and safety of DHA and DHA-algal oil ingredients from both clinical studies in humans as well as animals is extensive and is sufficient to support the safety and GRAS status of the DHA-algal oil product from *Schizochytrium* sp. G 3.
- Because this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

The safety and GRAS status of the DHA-algal oil product from *Schizochytrium* sp. G 3 that is the subject of this self-determination has been determined through the deliberations of a GRAS Panel of qualified experts convened by Mara and composed of Paul Damian,

Ph.D., M.P.H., DABT, ERT; Carol A. Knight, Ph.D.; and Stanley M. Tarka, Jr., Ph.D., F.A.T.S. These individuals are qualified by scientific training and experience to evaluate the safety of substances intended to be added to food. They have critically reviewed and evaluated the publicly available information summarized in this document and have individually and collectively concluded that the DHA-algal oil product from *Schizochytrium* sp. G 3, produced consistent with cGMP and meeting the specifications described herein, is safe under its intended conditions of use. The Panel further unanimously concluded that use of this DHA-algal oil product in human food is GRAS based on scientific procedures, and that other experts qualified to assess the safety of food and food ingredients for human consumption would concur with these conclusions. The Panel's GRAS opinion is included as Exhibit 1 to this document.

It is also Mara's opinion that other qualified scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. Mara has concluded that this DHA-algal oil is GRAS under the intended conditions of use on the basis of scientific procedures; and therefore, it is excluded from the definition of a food additive and may be marketed and sold for its intended purpose in the U.S. without the promulgation of a food additive regulation under Title 21 of the CFR.

Mara is not aware of any information that would be inconsistent with a finding that the proposed use of this DHA-rich algal oil product in food for human consumption meeting appropriate specifications, and used according to GMP, is safe and GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

§ 170.250 Part 7, Supporting Data and Information

The following references are all generally available, unless otherwise noted. Appendices A and B (analytical COAs for DHA-algal oil and material safety data sheets) are not generally available but are attached for reference.

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APPENDIX A

Certificates of Analysis/Algal Toxin Analysis

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MARA RENEWABLES CORPORATION
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CANADA

Reporting Date 01/24/2020

AR-19-QA-078735-06

REPORT OF ANALYSIS

This analytical report supersedes AR-19-QA-078735-05.

Sample Code 468-2019-10240045

Sample Description ALGAL OIL
Client Sample Code N-2-022-R-G3
Sample Reference RBD ALGAL OIL (022)

Reception Date 10/24/2019
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 295301

Test Results	Result
QA383 - Moisture & Volatiles (Air Oven 130C)	
Completion Date: 10/28/2019 **Method:** AOCS Ca 2c-25	
* Moisture & Volatiles	<0.01 %
QA818 - Crude Protein (Combustion)	
Completion Date: 10/30/2019 **Method:** AOAC 992.15	
* Crude Protein	<0.1 g/100 g
QA273 - Fat, Total (GC Method / NLEA)	
Completion Date: 11/04/2019 **Method:** AOAC 996.06	
* Total of Trans Fatty Acid Isomers	<0.05 g/100 g
QA137 - Ash	
Completion Date: 10/30/2019 **Method:** AOCS Ca 11-55	
* Ash	<0.10 %
QA133 - Arsenic (ICP-MS)	
Completion Date: 10/29/2019 **Method:** AOAC 2013.06	
Arsenic (As)	<0.02 mg/kg

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Eurofins Sample Code: 468-2019-10240045 **Client Sample Code: N-2-022-R-G3**

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Test Results	Result
QA205 - Cadmium (ICP-MS)	
Completion Date: 10/29/2019 **Method:** AOAC 2013.06	
Cadmium (Cd)	<0.01 mg/kg
QA227 - Chromium (SolD-ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Chromium (Cr)	<0.1 mg/kg
QA230 - Copper (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Copper (Cu)	<0.01 mg/kg
QA278 - Iron (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Iron (Fe)	<0.020 mg/kg
QA417 - Lead (ICP-MS)	
Completion Date: 10/29/2019 **Method:** AOAC 2013.06	
Lead (Pb)	<0.02 mg/kg
QA302 - Magnesium (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Magnesium (Mg)	<0.1 mg/kg
QA373 - Manganese (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Manganese (Mn)	<0.01 mg/kg
QD610 - Mercury (ICP-MS)	
Completion Date: 10/29/2019 **Method:** AOAC 2013.06	
Mercury (Hg)	<0.010 mg/kg
QA395 - Nickel (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Nickel (Ni)	<0.1 mg/kg

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Test Results	Result
QA413 - Phosphorus (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 20-99, mod.	
* Phosphorus (P)	<1.0 mg/kg
QA04H - Potassium (ICP-AES)	
Completion Date: 10/30/2019 **Method:** AOCS Ca 17-01	
* Potassium	<1.0 mg/kg
QA867 - Silicon (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Silicon (Si)	<1.0 mg/kg
QA388 - Sodium (ICP-AES)	
Completion Date: 11/04/2019 **Method:** AOCS Ca 17-01	
* Sodium	1.9 mg/kg
QA849 - Sulfur (ICP-AES)	
Completion Date: 10/28/2019 **Method:** AOCS Ca 17-01	
* Sulfur	5.2 mg/kg
QAA21 - Zinc (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Zinc (Zn)	<0.1 mg/kg
QA00I - Acid Value	
Completion Date: 10/28/2019 **Method:** AOCS Cd 3d-63	
Free fatty acids (as oleic acid)	0.06 %
Acid value (mg KOH/g)	0.12 mg KOH/g
QA117 - Anisidine Value (ISO Method)	
Completion Date: 10/28/2019 **Method:** ISO 6885	
* Anisidine Value	<1.0
QA221 - Color (Gardner)	
Completion Date: 10/30/2019 **Method:** AOCS Td-1a-64	

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Test Results	Result
* Color, Gardner	1 minus
QA328 - Insoluble Impurities	
Completion Date: 10/28/2019 **Method:** AOCS Ca 3a-46	
Insoluble impurities	<0.01 %
QA00F - Peroxide Value	
Completion Date: 10/24/2019 **Method:** AOCS Cd 8-53	
Peroxide value	0.37 meq/kg
QA934 - Trans Fatty Acids, relative area% (GC-FID)	
Completion Date: 11/01/2019 **Method:** AOCS 2a-94	
* total trans fatty acids C18:1	0.04 %
* total trans fatty acids C18:2 (without CLA)	<0.02 %
* total trans fatty acids C18:3	<0.02 %
* total trans fatty acids C18:2 + C18:3	<0.01 % of fatty acids
* Total Trans Fatty Acids	<0.05 %
QA966 - Unsaponifiable Matter	
Completion Date: 10/29/2019 **Method:** AOCS Ca 6a-40	
* Unsaponifiable matter	0.56 %
QA21S - Sterol Composition (GC-FID)	
Completion Date: 11/01/2019 **Method:** COI/T.20/ Doc. No 10	
Total sterol	2,850 mg/kg fat
Apparent Beta-Sitosterol (%tot. sterols)	26.78 %
Cholesterol (% total sterols)	55.47 %
Brassicasterol (% total sterols)	0.59 %
Campesterol (% total sterols)	<0.01 %
Campestanol (% total sterols)	<0.01 %
Stigmasterol (% total sterols)	9.79 %
delta-7-Campesterol (% total sterols)	5.81 %
Delta-5,23-stigmastadienol (% total ster.)	<0.01 %
Clerosterol (% total sterols)	19.41 %
Beta-Sitosterol "real" (% total sterols)	3.58 %
Sitostanol (% total sterols)	0.40 %

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AR-19-QA-078735-06

REPORT OF ANALYSIS

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Test Results	Result
Delta-5-avenasterol (% total sterols)	0.30 %
Delta-5,24-stigmastadienol (% total sterols)	3.10 %
Delta-7-stigmastenol (% total sterols)	0.92 %
Delta-7-avenasterol (% total sterols)	0.20 %
24-Methylene-cholesterol (% tot. sterol)	0.45 %

QA22C - Tocopherol Content (HPLC)
Completion Date: 10/31/2019 **Method:** ISO 9936:2006

* Alpha-Tocopherol	136 mg/kg
* Beta-Tocopherol	27.5 mg/kg
* Gamma-Tocopherol	1,250 mg/kg
* Delta-Tocopherol	680 mg/kg

QA20K - Fatty Acid Profile Extended
Completion Date: 12/02/2019 **Method:** Internal method

* C 6:0 (Caproic acid)	<0.1 mg/g
* C 6:0 (Caproic acid)	<0.1 %
* C 8:0 (Caprylic acid)	<0.1 mg/g
* C 8:0 (Caprylic acid)	<0.1 %
* C 10:0 (Capric acid)	0.7 mg/g
* C 10:0 (Capric acid)	0.1 %
* C 12:0 (Lauric acid)	1.3 mg/g
* C 12:0 (Lauric acid)	0.1 %
* C 13:0 (Tridecanoic acid)	<0.1 mg/g
* C 13:0 (Tridecanoic acid)	<0.1 %
* C 14:0 (Myristic acid)	23.3 mg/g
* C 14:0 (Myristic acid)	3.3 %
* C 14:1n5 (Myristoleic acid)	<0.1 mg/g
* C 14:1n5 (Myristoleic acid)	<0.1 %
* C 15:0 (Pentadecanoic acid)	1.8 mg/g
* C 15:0 (Pentadecanoic acid)	0.2 %
* C 15:1 (Pentadecenoic acid)	0.7 mg/g
* C 15:1 (Pentadecenoic acid)	0.1 %
* C 16:0 (Palmitic acid)	268.1 mg/g
* C 16:0 (Palmitic acid)	26.1 %

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Test Results	Result
* C 16:1n11 (Hexadecenoic Acid)	0.4 mg/g
* C 16:1n11 (Hexadecenoic Acid)	<0.1 %
* C 16:1n5 (Hexadecenoic Acid)	<0.1 mg/g
* C 16:1n5 (Hexadecenoic Acid)	<0.1 %
* C 16:1n7 (Palmitoleic acid)	3.5 mg/g
* C 16:1n7 (Palmitoleic acid)	0.3 %
* C 16:1n9 (Hexadecenoic acid)	<0.1 mg/g
* C 16:1n9 (Hexadecenoic acid)	<0.1 %
* C 16:2n4 (Hexadecadienoic acid)	<0.1 mg/g
* C 16:2n4 (Hexadecadienoic acid)	<0.1 %
* C 16:4n1 (Hexadecenoic acid)	14.5 mg/g
* C 16:4n1 (Hexadecenoic acid)	1.5 %
* C 17:0 (Margaric acid)	0.5 mg/g
* C 17:0 (Margaric acid)	0.1 %
* C 17:1n8 (Margaroleic acid)	1.9 mg/g
* C 17:1n8 (Margaroleic acid)	0.2 %
* C 18:0 (Stearic acid)	7.2 mg/g
* C 18:0 (Stearic acid)	0.7 %
* C 18:1n11 (Octadecenoic acid)	0.3 mg/g
* C 18:1n11 (Octadecenoic acid)	<0.1 %
* C 18:1n5 (Octadecenoic acid)	0.9 mg/g
* C 18:1n5 (Octadecenoic acid)	0.2 %
* C 18:1n7 (Vaccenic acid)	2.6 mg/g
* C 18:1n7 (Vaccenic acid)	0.3 %
* C 18:1n9 (Oleic acid)	2.6 mg/g
* C 18:1n9 (Oleic acid)	0.3 %
* C 18:2n-4 (Linoleic acid)	<0.1 mg/g
* C 18:2n-4 (Linoleic acid)	<0.1 %
* C 18:2n6 (Linoleic Acid)	0.2 mg/g
* C 18:2n6 (Linoleic Acid)	<0.1 %
* C 18:3n3 (alpha-Linolenic acid)	1.0 mg/g
* C 18:3n3 (alpha-Linolenic acid)	0.1 %
* C 18:3n6 (gamma-Linolenic acid)	0.4 mg/g
* C 18:3n6 (gamma-Linolenic acid)	<0.1 %
* C 18-4n3 (Steridonic acid)	1.3 mg/g

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AR-19-QA-078735-06

REPORT OF ANALYSIS

This analytical report supersedes AR-19-QA-078735-05.

Test Results	Result
* C 18-4n3 (Steridonic acid)	0.1 %
* C 20:0 (Arachidic acid)	1.7 mg/g
* C 20:0 (Arachidic acid)	0.2 %
* C 20:1n11 (Eicosenoic acid)	<0.1 mg/g
* C 20:1n11 (Eicosenoic acid)	<0.1 %
* C 20:1n7 (Eicosenoic acid)	<0.1 mg/g
* C 20:1n7 (Eicosenoic acid)	<0.1 %
* C 20:1n9 (Eicosenoic acid)	<0.1 mg/g
* C 20:1n9 (Eicosenoic acid)	<0.1 %
* C 20:2n6 (Eicosadienoic acid)	<0.1 mg/g
* C 20:2n6 (Eicosadienoic acid)	<0.1 %
* C 20:3n3 (Eicosatrienoic acid)	<0.1 mg/g
* C 20:3n3 (Eicosatrienoic acid)	<0.1 %
* C 20:3n6 (homo-gamma-Linolenic acid)	1.0 mg/g
* C 20:3n6 (homo-gamma-Linolenic acid)	0.1 %
* C 20:4n3 (Eicosatetraenoic acid)	5.6 mg/g
* C 20:4n3 (Eicosatetraenoic acid)	0.6 %
* C 20:4n6 (Arachidonic acid)	0.8 mg/g
* C 20:4n6 (Arachidonic acid)	0.1 %
* C 20:5n3 (EPA - Eicosapentaenoic acid)	4.6 mg/g
* C 20:5n3 (EPA - Eicosapentaenoic acid)	0.5 %
* C 21:0 (Heneicosanoic acid)	0.3 mg/g
* C 21:0 (Heneicosanoic acid)	<0.1 %
* C 21:5n3 (Heneicosapentaenoic acid)	<0.1 mg/g
* C 21:5n3 (Heneicosapentaenoic acid)	<0.1 %
* C 22:0 (Behenic acid)	0.8 mg/g
* C 22:0 (Behenic acid)	0.1 %
* C 22:1n11 (Cetoleic acid)	<0.1 mg/g
* C 22:1n11 (Cetoleic acid)	<0.1 %
* C 22:1n7 (Docosenoic acid)	11.0 mg/g
* C 22:1n7 (Docosenoic acid)	1.1 %
* C 22:1n9 (Erucic acid)	<0.1 mg/g
* C 22:1n9 (Erucic acid)	<0.1 %
* C 22:2n6 (Docosadienoic acid)	<0.1 mg/g
* C 22:2n6 (Docosadienoic acid)	<0.1 %

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Test Results	Result
* C 22:4n3 (Docosatetraenoic acid)	0.5 mg/g
* C 22:4n3 (Docosatetraenoic acid)	0.1 %
* C 22:5n3 (DPA - Docosapentaenoic acid)	0.7 mg/g
* C 22:5n3 (DPA - Docosapentaenoic acid)	0.1 %
* C 22:5n6 (DPA - Docosapentaenoic acid)	76.2 mg/g
* C 22:5n6 (DPA - Docosapentaenoic acid)	7.7 %
* C 22:6n3 (DHA - Docosahexaenoic acid)	546.4 mg/g
* C 22:6n3 (DHA - Docosahexaenoic acid)	54.0 %
* C 23:0 (Tricosanoic acid)	0.6 mg/g
* C 23:0 (Tricosanoic acid)	0.1 %
* C 24:0 (Lignoceric acid)	0.5 mg/g
* C 24:0 (Lignoceric acid)	<0.1 %
* C 24:1n9 (Nervonic acid)	1.8 mg/g
* C 24:1n9 (Nervonic acid)	0.2 %
* Omega-3 fatty acids	560.0 mg/g
* Omega-3 fatty acids	55.4 %
* Omega-4,5,7,8 & 11 fatty Acids	5.9 mg/g
* Omega-4,5,7,8 & 11 fatty Acids	0.6 %
* Omega-6 fatty acids	79.1 mg/g
* Omega-6 fatty acids	8.0 %
* Omega-9 fatty acids	15.5 mg/g
* Omega-9 fatty acids	1.6 %
* Unknown Components	14.0 mg/g
* Unknown Components	<0.1 %

QA25G - PAH Light and Heavy (GC-MSMS)
Completion Date: 11/12/2019 **Method:**

* 5-Methylchrysene	<1.0 µg/kg
* Benz(a)anthracene	<0.5 µg/kg
* Benzo(b)fluoranthene	<0.5 µg/kg
* Benzo-(c)-fluorene	<1.0 µg/kg
* Benzo-(j)-fluoranthen	<0.5 µg/kg
* Benzo(k)fluoranthene	<0.5 µg/kg
* Chrysene	<0.5 µg/kg
* Cyclopenta(c,d)pyrene	<1.0 µg/kg

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Test Results	Result
* Benzo(a)pyrene	<0.5 µg/kg
* Benzo(g,h,i)perylene	<0.5 µg/kg
* Dibenz(a,h)anthracene	<2.0 µg/kg
* Dibenzo(a,e)pyrene	<3.0 µg/kg
* Dibenzo(a,h)pyrene	<3.0 µg/kg
* Dibenzo(a,i)pyrene	<3.0 µg/kg
* Dibenzo(a,l)pyrene	<3.0 µg/kg
* Indeno(1,2,3-cd)pyrene	<2.0 µg/kg

UMDE0 - Aerobic Plate Count - AOAC 990.12
Completion Date: 10/31/2019 **Method:** AOAC 990.12

* Aerobic Plate Count	< 10 cfu/g

UMKP7 - Coliforms - BAM Chapter 4
Completion Date: 10/31/2019 **Method:** FDA BAM Chapter 4

* Total Coliforms	< 3 MPN/g

GFL01 - Dioxins and Furans (17 PCDD/F)
Completion Date: 11/04/2019 **Method:** Internal

* 2,3,7,8-TetraCDD	<0.0314 pg/g
* 1,2,3,7,8-PentaCDD	<0.0413 pg/g
* 1,2,3,4,7,8-HexaCDD	<0.0627 pg/g
* 1,2,3,6,7,8-HexaCDD	<0.0858 pg/g
* 1,2,3,7,8,9-HexaCDD	<0.0809 pg/g
* 1,2,3,4,6,7,8-HeptaCDD	<0.132 pg/g
* OctaCDD	<0.957 pg/g
* 2,3,7,8-TetraCDF	<0.0858 pg/g
* 1,2,3,7,8-PentaCDF	<0.0594 pg/g
* 2,3,4,7,8-PentaCDF	<0.0924 pg/g
* 1,2,3,4,7,8-HexaCDF	<0.0974 pg/g
* 1,2,3,6,7,8-HexaCDF	<0.0891 pg/g
* 1,2,3,7,8,9-HexaCDF	<0.0660 pg/g
* 2,3,4,6,7,8-HexaCDF	<0.0809 pg/g
* 1,2,3,4,6,7,8-HeptaCDF	<0.0924 pg/g
* 1,2,3,4,7,8,9-HeptaCDF	<0.0644 pg/g
* OctaCDF	<0.198 pg/g

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REPORT OF ANALYSIS

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Test Results	Result
* WHO(2005)-PCDD/F TEQ (lower-bound)	ND
* WHO(2005)-PCDD/F TEQ (medium-bound)	0.0851 pg/g
* WHO(2005)-PCDD/F TEQ (upper-bound)	0.170 pg/g

LW0XC - DSP-toxins, okadaicacid, DTX, AZA, PTX, YTX
Completion Date: 10/30/2019 **Method:** SLV K1-f5-m602.1 2009 mod.

* DST-total	<30 µg OA eq/kg
* AZA-total	<30 µg AZA eq/kg
* PTX-total	<30 µg PTX eq/kg
* YTX-total	<0.10 mg YTX eq/kg
* Okadaic acid	<30 µg OA eq/kg
* DTX-1	<30 µg OA eq/kg
* DTX-2	<30 µg OA eq/kg
* OA-acyl	<30 µg OA eq/kg
* DTX1-acyl	<30 µg OA eq/kg
* DTX2-acyl	<30 µg OA eq/kg
* AZA-1	<30 µg AZA eq/kg
* AZA-2	<30 µg AZA eq/kg
* AZA-3	<30 µg AZA eq/kg
* PTX-1	<30 µg PTX eq/kg
* PTX-2	<30 µg PTX eq/kg
* YTX	<0.10 mg YTX eq/kg
* 45-OH-YTX	<0.10 mg YTX eq/kg
* Homo-YTX	<0.10 mg YTX eq/kg
* 45-OH-homo-YTX	<0.10 mg YTX eq/kg
* Carboxy-YTX	<0.10 mg YTX eq/kg
* 45-OH-carboxy-YTX	<0.10 mg YTX eq/kg
* SPX-1	<30 µg/kg
* Amnesic Shellfish Poison, Domoic acid	<3.0 µg/g

UMVUE - Escherichia coli - BAM Chapter 4
Completion Date: 10/31/2019 **Method:** FDA BAM Chapter 4

* E. coli	< 3 MPN/g

UMYVR - Faecal Coliforms - BAM Chapter 4
Completion Date: 10/31/2019 **Method:** FDA BAM Chapter 4

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Eurofins Sample Code: 468-2019-10240045 **Client Sample Code: N-2-022-R-G3**

REPORT OF ANALYSIS

AR-19-QA-078735-06

This analytical report supersedes AR-19-QA-078735-05.

Test Results	Result
* Fecal Coliforms	< 3 MPN/g
UM4BV - Moulds - BAM Chapter 18	
Completion Date: 10/31/2019 **Method:** FDA BAM Chapter 18	
* Mold	< 10 cfu/g
UM4BV - Yeast - BAM Chapter 18	
Completion Date: 10/31/2019 **Method:** FDA BAM Chapter 18	
* Yeast	< 10 cfu/g
GFL07 - polychlorinated biphenyls (12 WHO PCB + 6 ICES PCB)	
Completion Date: 11/04/2019 **Method:** Internal	
* PCB 77	<2.97 pg/g
* PCB 81	<0.446 pg/g
* PCB 105	<6.44 pg/g
* PCB 114	<0.875 pg/g
* PCB 118	<23.1 pg/g
* PCB 123	<0.660 pg/g
* PCB 126	<0.413 pg/g
* PCB 156	<3.63 pg/g
* PCB 157	<0.677 pg/g
* PCB 167	<1.82 pg/g
* PCB 169	<1.98 pg/g
* PCB 189	<0.660 pg/g
* WHO(2005)-PCB TEQ (lower-bound)	ND
* WHO(2005)-PCB TEQ (medium-bound)	0.0511 g/kg
* WHO(2005)-PCB TEQ (upper-bound)	0.102 pg/g
* PCB 28	<0.165 ng/g
* PCB 52	<0.165 ng/g
* PCB 101	<0.165 ng/g
* PCB 138	<0.165 ng/g
* PCB 153	<0.165 ng/g
* PCB 180	<0.165 ng/g
* Total 6 ndl-PCB (lower-bound)	ND
* Total 6 ndl-PCB (medium-bound)	0.495 ng/g
* Total 6 ndl-PCB (upper-bound)	0.990 ng/g

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AR-19-QA-078735-06

REPORT OF ANALYSIS

This analytical report supersedes AR-19-QA-078735-05.

Test Results	Result
UMDTC - Salmonella - AOAC-RI 121501	
Completion Date: 10/31/2019 **Method:** AOAC-RI 121501	
* Salmonella	Not Detected per 25 g
UMHBM - Staphylococcus aureus - BAM Chapter 12	
Completion Date: 10/31/2019 **Method:** BAM Chapter 12	
* Staphylococcus aureus	< 10 cfu/g
GFTE1 - TEQ-Totals WHO-PCDD/F and PCB	
Completion Date: 11/04/2019 **Method:** Internal	
* WHO(2005)-PCDD/F+PCB TEQ (lower-bound)	ND
* WHO(2005)-PCDD/F+PCB TEQ (medium-bound)	0.136 pg/g
* WHO(2005)-PCDD/F+PCB TEQ (upper-bound)	0.272 pg/g

**This is not covered by our current A2LA accreditation.*

Respectfully Submitted,
Eurofins Central Analytical Laboratories

Victoria Siegel, Analytical Service Manager

Results shown in this report relate solely to the item submitted for analysis.
Uncertainty can be obtained upon request.

ACCREDITED TESTING CERT #2993-01

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CANADA

Reporting Date 01/24/2020

AR-19-QA-078736-06

REPORT OF ANALYSIS

This analytical report supersedes AR-19-QA-078736-05.

Sample Code 468-2019-10240046

Sample Description ALGAL OIL
Client Sample Code N-2-024-R-G3
Sample Reference RBD ALGAL OIL (024)

Reception Date 10/24/2019
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 295301

Test Results	Result
QA383 - Moisture & Volatiles (Air Oven 130C)	
Completion Date: 10/28/2019 **Method:** AOCS Ca 2c-25	
* Moisture & Volatiles	<0.01 %
QA818 - Crude Protein (Combustion)	
Completion Date: 10/30/2019 **Method:** AOAC 992.15	
* Crude Protein	<0.1 g/100 g
QA137 - Ash	
Completion Date: 10/30/2019 **Method:** AOCS Ca 11-55	
* Ash	<0.10 %
QA133 - Arsenic (ICP-MS)	
Completion Date: 10/29/2019 **Method:** AOAC 2013.06	
Arsenic (As)	<0.02 mg/kg
QA205 - Cadmium (ICP-MS)	
Completion Date: 10/29/2019 **Method:** AOAC 2013.06	
Cadmium (Cd)	<0.01 mg/kg

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Eurofins Sample Code: 468-2019-10240046 **Client Sample Code: N-2-024-R-G3**

AR-19-QA-078736-06

REPORT OF ANALYSIS

This analytical report supersedes AR-19-QA-078736-05.

Test Results	Result
QA227 - Chromium (SolD-ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Chromium (Cr)	<0.1 mg/kg
QA230 - Copper (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Copper (Cu)	<0.01 mg/kg
QA278 - Iron (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Iron (Fe)	0.036 mg/kg
QA417 - Lead (ICP-MS)	
Completion Date: 10/29/2019 **Method:** AOAC 2013.06	
Lead (Pb)	<0.02 mg/kg
QA302 - Magnesium (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Magnesium (Mg)	<0.1 mg/kg
QA373 - Manganese (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Manganese (Mn)	<0.01 mg/kg
QD610 - Mercury (ICP-MS)	
Completion Date: 10/29/2019 **Method:** AOAC 2013.06	
Mercury (Hg)	<0.010 mg/kg
QA395 - Nickel (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Nickel (Ni)	<0.1 mg/kg
QA413 - Phosphorus (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 20-99, mod.	
* Phosphorus (P)	<1.0 mg/kg

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AR-19-QA-078736-06

REPORT OF ANALYSIS

This analytical report supersedes AR-19-QA-078736-05.

Test Results	Result
QA04H - Potassium (ICP-AES)	
Completion Date: 10/30/2019 **Method:** AOCS Ca 17-01	
* Potassium	<1.0 mg/kg
QA867 - Silicon (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Silicon (Si)	1.2 mg/kg
QA388 - Sodium (ICP-AES)	
Completion Date: 11/04/2019 **Method:** AOCS Ca 17-01	
* Sodium	1.9 mg/kg
QA849 - Sulfur (ICP-AES)	
Completion Date: 10/28/2019 **Method:** AOCS Ca 17-01	
* Sulfur	5.8 mg/kg
QAA21 - Zinc (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Zinc (Zn)	<0.1 mg/kg
QA00I - Acid Value	
Completion Date: 10/28/2019 **Method:** AOCS Cd 3d-63	
Free fatty acids (as oleic acid)	0.06 %
Acid value (mg KOH/g)	0.11 mg KOH/g
QA117 - Anisidine Value (ISO Method)	
Completion Date: 10/28/2019 **Method:** ISO 6885	
* Anisidine Value	1.2
QA221 - Color (Gardner)	
Completion Date: 10/30/2019 **Method:** AOCS Td-1a-64	
* Color, Gardner	1 plus
QA328 - Insoluble Impurities	
Completion Date: 10/28/2019 **Method:** AOCS Ca 3a-46	

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REPORT OF ANALYSIS

AR-19-QA-078736-06

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Test Results	Result
Insoluble impurities	0.01 %
QA00F - Peroxide Value	
Completion Date: 10/24/2019 **Method:** AOCS Cd 8-53	
Peroxide value	0.52 meq/kg
QA934 - Trans Fatty Acids, relative area% (GC-FID)	
Completion Date: 11/01/2019 **Method:** AOCS 2a-94	
* total trans fatty acids C18:1	0.04 %
* total trans fatty acids C18:2 (without CLA)	<0.02 %
* total trans fatty acids C18:3	<0.02 %
* total trans fatty acids C18:2 + C18:3	<0.01 % of fatty acids
* Total Trans Fatty Acids	<0.05 %
QA966 - Unsaponifiable Matter	
Completion Date: 10/29/2019 **Method:** AOCS Ca 6a-40	
* Unsaponifiable matter	0.59 %
QA21S - Sterol Composition (GC-FID)	
Completion Date: 11/01/2019 **Method:** COI/T.20/ Doc. No 10	
Total sterol	2,760 mg/kg fat
Apparent Beta-Sitosterol (%tot. sterols)	27.86 %
Cholesterol (% total sterols)	50.35 %
Brassicasterol (% total sterols)	1.16 %
Campesterol (% total sterols)	<0.01 %
Campestanol (% total sterols)	<0.01 %
Stigmasterol (% total sterols)	11.31 %
delta-7-Campesterol (% total sterols)	7.00 %
Delta-5,23-stigmastadienol (% total ster.)	<0.01 %
Clerosterol (% total sterols)	19.30 %
Beta-Sitosterol "real" (% total sterols)	4.22 %
Sitostanol (% total sterols)	0.38 %
Delta-5-avenasterol (% total sterols)	0.24 %
Delta-5,24-stigmastadienol (% total sterols)	3.72 %
Delta-7-stigmastenol (% total sterols)	1.36 %
Delta-7-avenasterol (% total sterols)	0.44 %

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AR-19-QA-078736-06

REPORT OF ANALYSIS

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Test Results	Result
24-Methylene-cholesterol (% tot. sterol)	0.51 %
QA22C - Tocopherol Content (HPLC)	
Completion Date: 10/31/2019 **Method:** ISO 9936:2006	
* Alpha-Tocopherol	92.5 mg/kg
* Beta-Tocopherol	24.9 mg/kg
* Gamma-Tocopherol	1,100 mg/kg
* Delta-Tocopherol	620 mg/kg
QA20K - Fatty Acid Profile Extended	
Completion Date: 12/02/2019 **Method:** Internal method	
* C 6:0 (Caproic acid)	<0.1 mg/g
* C 6:0 (Caproic acid)	<0.1 %
* C 8:0 (Caprylic acid)	<0.1 mg/g
* C 8:0 (Caprylic acid)	<0.1 %
* C 10:0 (Capric acid)	1.1 mg/g
* C 10:0 (Capric acid)	0.1 %
* C 12:0 (Lauric acid)	0.9 mg/g
* C 12:0 (Lauric acid)	0.1 %
* C 13:0 (Tridecanoic acid)	<0.1 mg/g
* C 13:0 (Tridecanoic acid)	<0.1 %
* C 14:0 (Myristic acid)	19.2 mg/g
* C 14:0 (Myristic acid)	2.7 %
* C 14:1n5 (Myristoleic acid)	<0.1 mg/g
* C 14:1n5 (Myristoleic acid)	<0.1 %
* C 15:0 (Pentadecanoic acid)	3.1 mg/g
* C 15:0 (Pentadecanoic acid)	0.3 %
* C 15:1 (Pentadecenoic acid)	0.6 mg/g
* C 15:1 (Pentadecenoic acid)	0.1 %
* C 16:0 (Palmitic acid)	276.4 mg/g
* C 16:0 (Palmitic acid)	26.5 %
* C 16:1n11 (Hexadecenoic Acid)	0.4 mg/g
* C 16:1n11 (Hexadecenoic Acid)	<0.1 %
* C 16:1n5 (Hexadecenoic Acid)	0.1 mg/g
* C 16:1n5 (Hexadecenoic Acid)	<0.1 %

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REPORT OF ANALYSIS

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Test Results	Result
* C 16:1n7 (Palmitoleic acid)	2.3 mg/g
* C 16:1n7 (Palmitoleic acid)	0.2 %
* C 16:1n9 (Hexadecenoic acid)	<0.1 mg/g
* C 16:1n9 (Hexadecenoic acid)	<0.1 %
* C 16:2n4 (Hexadecadienoic acid)	<0.1 mg/g
* C 16:2n4 (Hexadecadienoic acid)	<0.1 %
* C 16:4n1 (Hexadecenoic acid)	22.4 mg/g
* C 16:4n1 (Hexadecenoic acid)	2.2 %
* C 17:0 (Margaric acid)	1.0 mg/g
* C 17:0 (Margaric acid)	0.1 %
* C 17:1n8 (Margaroleic acid)	2.9 mg/g
* C 17:1n8 (Margaroleic acid)	0.3 %
* C 18:0 (Stearic acid)	8.8 mg/g
* C 18:0 (Stearic acid)	0.9 %
* C 18:1n11 (Octadecenoic acid)	0.3 mg/g
* C 18:1n11 (Octadecenoic acid)	<0.1 %
* C 18:1n5 (Octadecenoic acid)	4.4 mg/g
* C 18:1n5 (Octadecenoic acid)	0.4 %
* C 18:1n7 (Vaccenic acid)	4.6 mg/g
* C 18:1n7 (Vaccenic acid)	0.5 %
* C 18:1n9 (Oleic acid)	2.8 mg/g
* C 18:1n9 (Oleic acid)	0.3 %
* C 18:2n-4 (Linoleic acid)	<0.1 mg/g
* C 18:2n-4 (Linoleic acid)	<0.1 %
* C 18:2n6 (Linoleic Acid)	0.2 mg/g
* C 18:2n6 (Linoleic Acid)	<0.1 %
* C 18:3n3 (alpha-Linolenic acid)	2.3 mg/g
* C 18:3n3 (alpha-Linolenic acid)	0.2 %
* C 18:3n6 (gamma-Linolenic acid)	0.6 mg/g
* C 18:3n6 (gamma-Linolenic acid)	0.1 %
* C 18-4n3 (Steridonic acid)	2.0 mg/g
* C 18-4n3 (Steridonic acid)	0.2 %
* C 20:0 (Arachidic acid)	1.2 mg/g
* C 20:0 (Arachidic acid)	0.1 %
* C 20:1n11 (Eicosenoic acid)	<0.1 mg/g

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AR-19-QA-078736-06

REPORT OF ANALYSIS

This analytical report supersedes AR-19-QA-078736-05.

Test Results	Result
* C 20:1n11 (Eicosenoic acid)	<0.1 %
* C 20:1n7 (Eicosenoic acid)	<0.1 mg/g
* C 20:1n7 (Eicosenoic acid)	<0.1 %
* C 20:1n9 (Eicosenoic acid)	<0.1 mg/g
* C 20:1n9 (Eicosenoic acid)	<0.1 %
* C 20:2n6 (Eicosadienoic acid)	<0.1 mg/g
* C 20:2n6 (Eicosadienoic acid)	<0.1 %
* C 20:3n3 (Eicosatrienoic acid)	<0.1 mg/g
* C 20:3n3 (Eicosatrienoic acid)	<0.1 %
* C 20:3n6 (homo-gamma-Linolenic acid)	1.2 mg/g
* C 20:3n6 (homo-gamma-Linolenic acid)	0.1 %
* C 20:4n3 (Eicosatetraenoic acid)	5.9 mg/g
* C 20:4n3 (Eicosatetraenoic acid)	0.6 %
* C 20:4n6 (Arachidonic acid)	0.9 mg/g
* C 20:4n6 (Arachidonic acid)	0.1 %
* C 20:5n3 (EPA - Eicosapentaenoic acid)	4.5 mg/g
* C 20:5n3 (EPA - Eicosapentaenoic acid)	0.5 %
* C 21:0 (Heneicosanoic acid)	0.3 mg/g
* C 21:0 (Heneicosanoic acid)	<0.1 %
* C 21:5n3 (Heneicosapentaenoic acid)	<0.1 mg/g
* C 21:5n3 (Heneicosapentaenoic acid)	<0.1 %
* C 22:0 (Behenic acid)	0.6 mg/g
* C 22:0 (Behenic acid)	0.1 %
* C 22:1n11 (Cetoleic acid)	<0.1 mg/g
* C 22:1n11 (Cetoleic acid)	<0.1 %
* C 22:1n7 (Docosenoic acid)	4.9 mg/g
* C 22:1n7 (Docosenoic acid)	0.5 %
* C 22:1n9 (Erucic acid)	<0.1 mg/g
* C 22:1n9 (Erucic acid)	<0.1 %
* C 22:2n6 (Docosadienoic acid)	<0.1 mg/g
* C 22:2n6 (Docosadienoic acid)	<0.1 %
* C 22:4n3 (Docosatetraenoic acid)	0.7 mg/g
* C 22:4n3 (Docosatetraenoic acid)	0.1 %
* C 22:5n3 (DPA - Docosapentaenoic acid)	1.0 mg/g
* C 22:5n3 (DPA - Docosapentaenoic acid)	0.1 %

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REPORT OF ANALYSIS

AR-19-QA-078736-06

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Test Results	Result
* C 22:5n6 (DPA - Docosapentaenoic acid)	90.0 mg/g
* C 22:5n6 (DPA - Docosapentaenoic acid)	9.0 %
* C 22:6n3 (DHA - Docosahexaenoic acid)	537.4 mg/g
* C 22:6n3 (DHA - Docosahexaenoic acid)	52.3 %
* C 23:0 (Tricosanoic acid)	1.2 mg/g
* C 23:0 (Tricosanoic acid)	0.1 %
* C 24:0 (Lignoceric acid)	0.5 mg/g
* C 24:0 (Lignoceric acid)	<0.1 %
* C 24:1n9 (Nervonic acid)	1.1 mg/g
* C 24:1n9 (Nervonic acid)	0.1 %
* Omega-3 fatty acids	553.7 mg/g
* Omega-3 fatty acids	54.0 %
* Omega-4,5,7,8 & 11 fatty Acids	6.7 mg/g
* Omega-4,5,7,8 & 11 fatty Acids	0.7 %
* Omega-6 fatty acids	93.3 mg/g
* Omega-6 fatty acids	9.3 %
* Omega-9 fatty acids	8.9 mg/g
* Omega-9 fatty acids	0.9 %
* Unknown Components	9.5 mg/g
* Unknown Components	<0.1 %

QA25G - PAH Light and Heavy (GC-MSMS)
Completion Date: 11/12/2019 **Method:**

* 5-Methylchrysene	<1.0 µg/kg
* Benz(a)anthracene	0.5 µg/kg
* Benzo(b)fluoranthene	0.6 µg/kg
* Benzo-(c)-fluorene	<1.0 µg/kg
* Benzo-(j)-fluoranthen	<0.5 µg/kg
* Benzo(k)fluoranthene	<0.5 µg/kg
* Chrysene	0.5 µg/kg
* Cyclopenta(c,d)pyrene	<1.0 µg/kg
* Benzo(a)pyrene	<0.5 µg/kg
* Benzo(g,h,i)perylene	<0.5 µg/kg
* Dibenz(a,h)anthracene	<2.0 µg/kg
* Dibenzo(a,e)pyrene	<3.0 µg/kg

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REPORT OF ANALYSIS

AR-19-QA-078736-06

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Test Results	Result
* Dibenzo(a,h)pyrene	<3.0 µg/kg
* Dibenzo(a,i)pyrene	<3.0 µg/kg
* Dibenzo(a,l)pyrene	<3.0 µg/kg
* Indeno(1,2,3-cd)pyrene	<2.0 µg/kg
UMDE0 - Aerobic Plate Count - AOAC 990.12	
Completion Date: 10/31/2019 **Method:** AOAC 990.12	
* Aerobic Plate Count	< 10 cfu/g
UMKP7 - Coliforms - BAM Chapter 4	
Completion Date: 10/31/2019 **Method:** FDA BAM Chapter 4	
* Total Coliforms	< 3 MPN/g
GFL13 - Dioxins and Furans (17 PCDD/F)	
Completion Date: 11/11/2019 **Method:** Internal	
* 2,3,7,8-TetraCDD	<0.0627 pg/g
* 1,2,3,7,8-PentaCDD	<0.0825 pg/g
* 1,2,3,4,7,8-HexaCDD	<0.125 pg/g
* 1,2,3,6,7,8-HexaCDD	<0.172 pg/g
* 1,2,3,7,8,9-HexaCDD	<0.162 pg/g
* 1,2,3,4,6,7,8-HeptaCDD	<0.264 pg/g
* OctaCDD	<1.91 pg/g
* 2,3,7,8-TetraCDF	<0.172 pg/g
* 1,2,3,7,8-PentaCDF	<0.119 pg/g
* 2,3,4,7,8-PentaCDF	<0.185 pg/g
* 1,2,3,4,7,8-HexaCDF	<0.195 pg/g
* 1,2,3,6,7,8-HexaCDF	<0.178 pg/g
* 1,2,3,7,8,9-HexaCDF	<0.132 pg/g
* 2,3,4,6,7,8-HexaCDF	<0.162 pg/g
* 1,2,3,4,6,7,8-HeptaCDF	<0.185 pg/g
* 1,2,3,4,7,8,9-HeptaCDF	<0.129 pg/g
* OctaCDF	<0.396 pg/g
* WHO(2005)-PCDD/F TEQ (lower-bound)	ND
* WHO(2005)-PCDD/F TEQ (medium-bound)	0.170 pg/g
* WHO(2005)-PCDD/F TEQ (upper-bound)	0.340 pg/g

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Eurofins Sample Code: 468-2019-10240046 **Client Sample Code: N-2-024-R-G3**

AR-19-QA-078736-06

REPORT OF ANALYSIS

This analytical report supersedes AR-19-QA-078736-05.

Test Results	Result
LW0XC - DSP-toxins, okadaicacid, DTX, AZA, PTX, YTX	
Completion Date: 10/30/2019 **Method:** SLV K1-f5-m602.1 2009 mod.	
* DST-total	<30 µg OA eq/kg
* AZA-total	<30 µg AZA eq/kg
* PTX-total	<30 µg PTX eq/kg
* YTX-total	<0.10 mg YTX eq/kg
* Okadaic acid	<30 µg OA eq/kg
* DTX-1	<30 µg OA eq/kg
* DTX-2	<30 µg OA eq/kg
* OA-acyl	<30 µg OA eq/kg
* DTX1-acyl	<30 µg OA eq/kg
* DTX2-acyl	<30 µg OA eq/kg
* AZA-1	<30 µg AZA eq/kg
* AZA-2	<30 µg AZA eq/kg
* AZA-3	<30 µg AZA eq/kg
* PTX-1	<30 µg PTX eq/kg
* PTX-2	<30 µg PTX eq/kg
* YTX	<0.10 mg YTX eq/kg
* 45-OH-YTX	<0.10 mg YTX eq/kg
* Homo-YTX	<0.10 mg YTX eq/kg
* 45-OH-homo-YTX	<0.10 mg YTX eq/kg
* Carboxy-YTX	<0.10 mg YTX eq/kg
* 45-OH-carboxy-YTX	<0.10 mg YTX eq/kg
* SPX-1	<30 µg/kg
* Amnesic Shellfish Poison, Domoic acid	<3.0 µg/g
UMVUE - Escherichia coli - BAM Chapter 4	
Completion Date: 10/31/2019 **Method:** FDA BAM Chapter 4	
* E. coli	< 3 MPN/g
UMYVR - Faecal Coliforms - BAM Chapter 4	
Completion Date: 10/31/2019 **Method:** FDA BAM Chapter 4	
* Fecal Coliforms	< 3 MPN/g
UM4BV - Moulds - BAM Chapter 18	
Completion Date: 10/31/2019 **Method:** FDA BAM Chapter 18	

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AR-19-QA-078736-06

REPORT OF ANALYSIS

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Test Results	Result
* Mold	< 10 cfu/g
UM4BV - Yeast - BAM Chapter 18	
Completion Date: 10/31/2019 **Method:** FDA BAM Chapter 18	
* Yeast	< 10 cfu/g
GFL14 - polychlorinated biphenyls (12 WHO PCB + 6 ICES PCB)	
Completion Date: 11/11/2019 **Method:** Internal	
* PCB 77	<5.94 pg/g
* PCB 81	<0.891 pg/g
* PCB 105	<12.9 pg/g
* PCB 114	<1.75 pg/g
* PCB 118	<46.2 pg/g
* PCB 123	<1.32 pg/g
* PCB 126	<0.825 pg/g
* PCB 156	<7.26 pg/g
* PCB 157	<1.35 pg/g
* PCB 167	<3.63 pg/g
* PCB 169	<3.96 pg/g
* PCB 189	<1.32 pg/g
* WHO(2005)-PCB TEQ (lower-bound)	ND
* WHO(2005)-PCB TEQ (medium-bound)	0.102 pg/g
* WHO(2005)-PCB TEQ (upper-bound)	0.204 pg/g
* PCB 28	<0.330 ng/g
* PCB 52	<0.330 ng/g
* PCB 101	<0.330 ng/g
* PCB 138	<0.330 ng/g
* PCB 153	<0.330 ng/g
* PCB 180	<0.330 ng/g
* Total 6 ndl-PCB (lower-bound)	ND
* Total 6 ndl-PCB (medium-bound)	0.990 ng/g
* Total 6 ndl-PCB (upper-bound)	1.98 ng/g
UMDTC - Salmonella - AOAC-RI 121501	
Completion Date: 10/31/2019 **Method:** AOAC-RI 121501	
* Salmonella	Not Detected per 25 g

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AR-19-QA-078736-06

REPORT OF ANALYSIS

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Test Results	Result
UMHBM - Staphylococcus aureus - BAM Chapter 12	
Completion Date: 10/31/2019 **Method:** BAM Chapter 12	
* Staphylococcus aureus	< 10 cfu/g
GFTE1 - TEQ-Totals WHO-PCDD/F and PCB	
Completion Date: 11/11/2019 **Method:** Internal	
* WHO(2005)-PCDD/F+PCB TEQ (lower-bound)	ND
* WHO(2005)-PCDD/F+PCB TEQ (medium-bound)	0.272 pg/g
* WHO(2005)-PCDD/F+PCB TEQ (upper-bound)	0.545 pg/g

**This is not covered by our current A2LA accreditation.*

Respectfully Submitted,
Eurofins Central Analytical Laboratories

Victoria Siegel, Analytical Service Manager

Results shown in this report relate solely to the item submitted for analysis.
Uncertainty can be obtained upon request.

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CANADA

Reporting Date 01/24/2020

AR-19-QA-078737-06

REPORT OF ANALYSIS

This analytical report supersedes AR-19-QA-078737-05.

Sample Code 468-2019-10240047

Sample Description ALGAL OIL
Client Sample Code N-2-026-R-G3
Sample Reference RBD ALGAL OIL (026)

Reception Date 10/24/2019
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order 295301

Test Results	Result
QA383 - Moisture & Volatiles (Air Oven 130C)	
Completion Date: 10/28/2019 **Method:** AOCS Ca 2c-25	
* Moisture & Volatiles	<0.01 %
QA818 - Crude Protein (Combustion)	
Completion Date: 10/30/2019 **Method:** AOAC 992.15	
* Crude Protein	<0.1 g/100 g
QA137 - Ash	
Completion Date: 10/30/2019 **Method:** AOCS Ca 11-55	
* Ash	<0.10 %
QA133 - Arsenic (ICP-MS)	
Completion Date: 10/29/2019 **Method:** AOAC 2013.06	
Arsenic (As)	<0.02 mg/kg
QA205 - Cadmium (ICP-MS)	
Completion Date: 10/29/2019 **Method:** AOAC 2013.06	
Cadmium (Cd)	<0.01 mg/kg

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Eurofins Sample Code: 468-2019-10240047 **Client Sample Code: N-2-026-R-G3**

AR-19-QA-078737-06

REPORT OF ANALYSIS

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Test Results	Result
QA227 - Chromium (SolD-ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Chromium (Cr)	<0.1 mg/kg
QA230 - Copper (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Copper (Cu)	<0.01 mg/kg
QA278 - Iron (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Iron (Fe)	<0.020 mg/kg
QA417 - Lead (ICP-MS)	
Completion Date: 10/29/2019 **Method:** AOAC 2013.06	
Lead (Pb)	<0.02 mg/kg
QA302 - Magnesium (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Magnesium (Mg)	<0.1 mg/kg
QA373 - Manganese (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Manganese (Mn)	<0.01 mg/kg
QD610 - Mercury (ICP-MS)	
Completion Date: 10/29/2019 **Method:** AOAC 2013.06	
Mercury (Hg)	<0.010 mg/kg
QA395 - Nickel (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Nickel (Ni)	<0.1 mg/kg
QA413 - Phosphorus (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 20-99, mod.	
* Phosphorus (P)	<1.0 mg/kg

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AR-19-QA-078737-06

REPORT OF ANALYSIS

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Test Results	Result
QA04H - Potassium (ICP-AES)	
Completion Date: 10/30/2019 **Method:** AOCS Ca 17-01	
* Potassium	<1.0 mg/kg
QA867 - Silicon (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Silicon (Si)	<1.0 mg/kg
QA388 - Sodium (ICP-AES)	
Completion Date: 11/04/2019 **Method:** AOCS Ca 17-01	
* Sodium	2.3 mg/kg
QA849 - Sulfur (ICP-AES)	
Completion Date: 10/28/2019 **Method:** AOCS Ca 17-01	
* Sulfur	5.1 mg/kg
QAA21 - Zinc (ICP-AES)	
Completion Date: 11/01/2019 **Method:** AOCS Ca 17-01	
* Zinc (Zn)	<0.1 mg/kg
QA00I - Acid Value	
Completion Date: 10/28/2019 **Method:** AOCS Cd 3d-63	
Free fatty acids (as oleic acid)	0.07 %
Acid value (mg KOH/g)	0.14 mg KOH/g
QA117 - Anisidine Value (ISO Method)	
Completion Date: 10/28/2019 **Method:** ISO 6885	
* Anisidine Value	<1.0
QA221 - Color (Gardner)	
Completion Date: 10/30/2019 **Method:** AOCS Td-1a-64	
* Color, Gardner	1 plus
QA328 - Insoluble Impurities	
Completion Date: 10/28/2019 **Method:** AOCS Ca 3a-46	

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AR-19-QA-078737-06

REPORT OF ANALYSIS

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Test Results	Result
Insoluble impurities	0.05 %
QA00F - Peroxide Value	
Completion Date: 10/24/2019 **Method:** AOCS Cd 8-53	
Peroxide value	0.41 meq/kg
QA934 - Trans Fatty Acids, relative area% (GC-FID)	
Completion Date: 11/01/2019 **Method:** AOCS 2a-94	
* total trans fatty acids C18:1	0.05 %
* total trans fatty acids C18:2 (without CLA)	<0.02 %
* total trans fatty acids C18:3	<0.02 %
* total trans fatty acids C18:2 + C18:3	<0.01 % of fatty acids
* Total Trans Fatty Acids	<0.05 %
QA966 - Unsaponifiable Matter	
Completion Date: 10/29/2019 **Method:** AOCS Ca 6a-40	
* Unsaponifiable matter	0.69 %
QA21S - Sterol Composition (GC-FID)	
Completion Date: 11/01/2019 **Method:** COI/T.20/ Doc. No 10	
Total sterol	2,430 mg/kg fat
Apparent Beta-Sitosterol (%tot. sterols)	30.22 %
Cholesterol (% total sterols)	48.27 %
Brassicasterol (% total sterols)	1.23 %
Campesterol (% total sterols)	0.29 %
Campestanol (% total sterols)	<0.01 %
Stigmasterol (% total sterols)	10.45 %
delta-7-Campesterol (% total sterols)	8.17 %
Delta-5,23-stigmastadienol (% total ster.)	<0.01 %
Clerosterol (% total sterols)	23.46 %
Beta-Sitosterol "real" (% total sterols)	3.49 %
Sitostanol (% total sterols)	0.31 %
Delta-5-avenasterol (% total sterols)	0.27 %
Delta-5,24-stigmastadienol (% total sterols)	2.69 %
Delta-7-stigmastenol (% total sterols)	0.92 %
Delta-7-avenasterol (% total sterols)	0.16 %

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REPORT OF ANALYSIS

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Test Results	Result
24-Methylene-cholesterol (% tot. sterol)	0.29 %
QA22C - Tocopherol Content (HPLC)	
Completion Date: 10/31/2019 **Method:** ISO 9936:2006	
* Alpha-Tocopherol	263 mg/kg
* Beta-Tocopherol	46.2 mg/kg
* Gamma-Tocopherol	2,030 mg/kg
* Delta-Tocopherol	1,100 mg/kg
QA20K - Fatty Acid Profile Extended	
Completion Date: 12/02/2019 **Method:** Internal method	
* C 6:0 (Caproic acid)	<0.1 mg/g
* C 6:0 (Caproic acid)	<0.1 %
* C 8:0 (Caprylic acid)	<0.1 mg/g
* C 8:0 (Caprylic acid)	<0.1 %
* C 10:0 (Capric acid)	1.1 mg/g
* C 10:0 (Capric acid)	0.1 %
* C 12:0 (Lauric acid)	1.1 mg/g
* C 12:0 (Lauric acid)	0.1 %
* C 13:0 (Tridecanoic acid)	<0.1 mg/g
* C 13:0 (Tridecanoic acid)	<0.1 %
* C 14:0 (Myristic acid)	17.9 mg/g
* C 14:0 (Myristic acid)	2.6 %
* C 14:1n5 (Myristoleic acid)	<0.1 mg/g
* C 14:1n5 (Myristoleic acid)	<0.1 %
* C 15:0 (Pentadecanoic acid)	2.1 mg/g
* C 15:0 (Pentadecanoic acid)	0.2 %
* C 15:1 (Pentadecenoic acid)	0.8 mg/g
* C 15:1 (Pentadecenoic acid)	0.1 %
* C 16:0 (Palmitic acid)	222.6 mg/g
* C 16:0 (Palmitic acid)	21.6 %
* C 16:1n11 (Hexadecenoic Acid)	0.4 mg/g
* C 16:1n11 (Hexadecenoic Acid)	<0.1 %
* C 16:1n5 (Hexadecenoic Acid)	<0.1 mg/g
* C 16:1n5 (Hexadecenoic Acid)	<0.1 %

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Test Results	Result
* C 16:1n7 (Palmitoleic acid)	2.6 mg/g
* C 16:1n7 (Palmitoleic acid)	0.3 %
* C 16:1n9 (Hexadecenoic acid)	<0.1 mg/g
* C 16:1n9 (Hexadecenoic acid)	<0.1 %
* C 16:2n4 (Hexadecadienoic acid)	<0.1 mg/g
* C 16:2n4 (Hexadecadienoic acid)	<0.1 %
* C 16:4n1 (Hexadecenoic acid)	20.0 mg/g
* C 16:4n1 (Hexadecenoic acid)	2.0 %
* C 17:0 (Margaric acid)	0.6 mg/g
* C 17:0 (Margaric acid)	0.1 %
* C 17:1n8 (Margaroleic acid)	1.7 mg/g
* C 17:1n8 (Margaroleic acid)	0.2 %
* C 18:0 (Stearic acid)	6.0 mg/g
* C 18:0 (Stearic acid)	0.6 %
* C 18:1n11 (Octadecenoic acid)	0.4 mg/g
* C 18:1n11 (Octadecenoic acid)	<0.1 %
* C 18:1n5 (Octadecenoic acid)	4.4 mg/g
* C 18:1n5 (Octadecenoic acid)	0.4 %
* C 18:1n7 (Vaccenic acid)	1.9 mg/g
* C 18:1n7 (Vaccenic acid)	0.2 %
* C 18:1n9 (Oleic acid)	2.6 mg/g
* C 18:1n9 (Oleic acid)	0.3 %
* C 18:2n-4 (Linoleic acid)	<0.1 mg/g
* C 18:2n-4 (Linoleic acid)	<0.1 %
* C 18:2n6 (Linoleic Acid)	0.4 mg/g
* C 18:2n6 (Linoleic Acid)	<0.1 %
* C 18:3n3 (alpha-Linolenic acid)	1.0 mg/g
* C 18:3n3 (alpha-Linolenic acid)	0.1 %
* C 18:3n6 (gamma-Linolenic acid)	0.5 mg/g
* C 18:3n6 (gamma-Linolenic acid)	<0.1 %
* C 18-4n3 (Steridonic acid)	1.6 mg/g
* C 18-4n3 (Steridonic acid)	0.2 %
* C 20:0 (Arachidic acid)	1.5 mg/g
* C 20:0 (Arachidic acid)	0.1 %
* C 20:1n11 (Eicosenoic acid)	<0.1 mg/g

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AR-19-QA-078737-06

REPORT OF ANALYSIS

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Test Results	Result
* C 20:1n11 (Eicosenoic acid)	<0.1 %
* C 20:1n7 (Eicosenoic acid)	<0.1 mg/g
* C 20:1n7 (Eicosenoic acid)	<0.1 %
* C 20:1n9 (Eicosenoic acid)	<0.1 mg/g
* C 20:1n9 (Eicosenoic acid)	<0.1 %
* C 20:2n6 (Eicosadienoic acid)	<0.1 mg/g
* C 20:2n6 (Eicosadienoic acid)	<0.1 %
* C 20:3n3 (Eicosatrienoic acid)	<0.1 mg/g
* C 20:3n3 (Eicosatrienoic acid)	<0.1 %
* C 20:3n6 (homo-gamma-Linolenic acid)	1.2 mg/g
* C 20:3n6 (homo-gamma-Linolenic acid)	0.1 %
* C 20:4n3 (Eicosatetraenoic acid)	6.1 mg/g
* C 20:4n3 (Eicosatetraenoic acid)	0.6 %
* C 20:4n6 (Arachidonic acid)	0.9 mg/g
* C 20:4n6 (Arachidonic acid)	0.1 %
* C 20:5n3 (EPA - Eicosapentaenoic acid)	4.6 mg/g
* C 20:5n3 (EPA - Eicosapentaenoic acid)	0.5 %
* C 21:0 (Heneicosanoic acid)	0.4 mg/g
* C 21:0 (Heneicosanoic acid)	<0.1 %
* C 21:5n3 (Heneicosapentaenoic acid)	<0.1 mg/g
* C 21:5n3 (Heneicosapentaenoic acid)	<0.1 %
* C 22:0 (Behenic acid)	0.7 mg/g
* C 22:0 (Behenic acid)	0.1 %
* C 22:1n11 (Cetoleic acid)	<0.1 mg/g
* C 22:1n11 (Cetoleic acid)	<0.1 %
* C 22:1n7 (Docosenoic acid)	9.8 mg/g
* C 22:1n7 (Docosenoic acid)	1.0 %
* C 22:1n9 (Erucic acid)	<0.1 mg/g
* C 22:1n9 (Erucic acid)	<0.1 %
* C 22:2n6 (Docosadienoic acid)	<0.1 mg/g
* C 22:2n6 (Docosadienoic acid)	<0.1 %
* C 22:4n3 (Docosatetraenoic acid)	0.7 mg/g
* C 22:4n3 (Docosatetraenoic acid)	0.1 %
* C 22:5n3 (DPA - Docosapentaenoic acid)	0.7 mg/g
* C 22:5n3 (DPA - Docosapentaenoic acid)	0.1 %

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AR-19-QA-078737-06

REPORT OF ANALYSIS

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Test Results	Result
* C 22:5n6 (DPA - Docosapentaenoic acid)	91.4 mg/g
* C 22:5n6 (DPA - Docosapentaenoic acid)	9.2 %
* C 22:6n3 (DHA - Docosahexaenoic acid)	582.7 mg/g
* C 22:6n3 (DHA - Docosahexaenoic acid)	57.4 %
* C 23:0 (Tricosanoic acid)	1.1 mg/g
* C 23:0 (Tricosanoic acid)	0.1 %
* C 24:0 (Lignoceric acid)	0.4 mg/g
* C 24:0 (Lignoceric acid)	<0.1 %
* C 24:1n9 (Nervonic acid)	1.7 mg/g
* C 24:1n9 (Nervonic acid)	0.2 %
* Omega-3 fatty acids	597.3 mg/g
* Omega-3 fatty acids	58.9 %
* Omega-4,5,7,8 & 11 fatty Acids	4.4 mg/g
* Omega-4,5,7,8 & 11 fatty Acids	0.5 %
* Omega-6 fatty acids	94.9 mg/g
* Omega-6 fatty acids	9.6 %
* Omega-9 fatty acids	14.2 mg/g
* Omega-9 fatty acids	1.5 %
* Unknown Components	11.8 mg/g
* Unknown Components	<0.1 %

QA25G - PAH Light and Heavy (GC-MSMS)
Completion Date: 11/12/2019 **Method:**

* 5-Methylchrysene	<1.0 µg/kg
* Benz(a)anthracene	<0.5 µg/kg
* Benzo(b)fluoranthene	<0.5 µg/kg
* Benzo-(c)-fluorene	<1.0 µg/kg
* Benzo-(j)-fluoranthen	<0.5 µg/kg
* Benzo(k)fluoranthene	<0.5 µg/kg
* Chrysene	<0.5 µg/kg
* Cyclopenta(c,d)pyrene	<1.0 µg/kg
* Benzo(a)pyrene	<0.5 µg/kg
* Benzo(g,h,i)perylene	<0.5 µg/kg
* Dibenz(a,h)anthracene	<2.0 µg/kg
* Dibenzo(a,e)pyrene	<3.0 µg/kg

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REPORT OF ANALYSIS

AR-19-QA-078737-06

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Test Results	Result
* Dibenzo(a,h)pyrene	<3.0 µg/kg
* Dibenzo(a,i)pyrene	<3.0 µg/kg
* Dibenzo(a,l)pyrene	<3.0 µg/kg
* Indeno(1,2,3-cd)pyrene	<2.0 µg/kg
UMDE0 - Aerobic Plate Count - AOAC 990.12	
Completion Date: 10/31/2019 **Method:** AOAC 990.12	
* Aerobic Plate Count	< 10 cfu/g
UMKP7 - Coliforms - BAM Chapter 4	
Completion Date: 10/31/2019 **Method:** FDA BAM Chapter 4	
* Total Coliforms	< 3 MPN/g
GFL01 - Dioxins and Furans (17 PCDD/F)	
Completion Date: 11/04/2019 **Method:** Internal	
* 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	<0.0618 pg/g
* 1,2,3,6,7,8-HexaCDD	<0.0846 pg/g
* 1,2,3,7,8,9-HexaCDD	<0.0797 pg/g
* 1,2,3,4,6,7,8-HeptaCDD	<0.130 pg/g
* OctaCDD	<0.943 pg/g
* 2,3,7,8-TetraCDF	<0.0846 pg/g
* 1,2,3,7,8-PentaCDF	<0.0585 pg/g
* 2,3,4,7,8-PentaCDF	<0.0911 pg/g
* 1,2,3,4,7,8-HexaCDF	<0.0959 pg/g
* 1,2,3,6,7,8-HexaCDF	<0.0878 pg/g
* 1,2,3,7,8,9-HexaCDF	<0.0650 pg/g
* 2,3,4,6,7,8-HexaCDF	<0.0797 pg/g
* 1,2,3,4,6,7,8-HeptaCDF	<0.0911 pg/g
* 1,2,3,4,7,8,9-HeptaCDF	<0.0634 pg/g
* OctaCDF	<0.195 pg/g
* WHO(2005)-PCDD/F TEQ (lower-bound)	ND
* WHO(2005)-PCDD/F TEQ (medium-bound)	0.0839 pg/g
* WHO(2005)-PCDD/F TEQ (upper-bound)	0.168 pg/g

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AR-19-QA-078737-06

REPORT OF ANALYSIS

This analytical report supersedes AR-19-QA-078737-05.

Test Results	Result
LW0XC - DSP-toxins, okadaicacid, DTX, AZA, PTX, YTX	
Completion Date: 10/30/2019 **Method:** SLV K1-f5-m602.1 2009 mod.	
* DST-total	<30 µg OA eq/kg
* AZA-total	<30 µg AZA eq/kg
* PTX-total	<30 µg PTX eq/kg
* YTX-total	<0.10 mg YTX eq/kg
* Okadaic acid	<30 µg OA eq/kg
* DTX-1	<30 µg OA eq/kg
* DTX-2	<30 µg OA eq/kg
* OA-acyl	<30 µg OA eq/kg
* DTX1-acyl	<30 µg OA eq/kg
* DTX2-acyl	<30 µg OA eq/kg
* AZA-1	<30 µg AZA eq/kg
* AZA-2	<30 µg AZA eq/kg
* AZA-3	<30 µg AZA eq/kg
* PTX-1	<30 µg PTX eq/kg
* PTX-2	<30 µg PTX eq/kg
* YTX	<0.10 mg YTX eq/kg
* 45-OH-YTX	<0.10 mg YTX eq/kg
* Homo-YTX	<0.10 mg YTX eq/kg
* 45-OH-homo-YTX	<0.10 mg YTX eq/kg
* Carboxy-YTX	<0.10 mg YTX eq/kg
* 45-OH-carboxy-YTX	<0.10 mg YTX eq/kg
* SPX-1	<30 µg/kg
* Amnesic Shellfish Poison, Domoic acid	<3.0 µg/g
UMVUE - Escherichia coli - BAM Chapter 4	
Completion Date: 10/31/2019 **Method:** FDA BAM Chapter 4	
* E. coli	< 3 MPN/g
UMYVR - Faecal Coliforms - BAM Chapter 4	
Completion Date: 10/31/2019 **Method:** FDA BAM Chapter 4	
* Fecal Coliforms	< 3 MPN/g
UM4BV - Moulds - BAM Chapter 18	
Completion Date: 10/31/2019 **Method:** FDA BAM Chapter 18	

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Eurofins Sample Code: 468-2019-10240047 **Client Sample Code: N-2-026-R-G3**

AR-19-QA-078737-06

REPORT OF ANALYSIS

This analytical report supersedes AR-19-QA-078737-05.

Test Results	Result
* Mold	< 10 cfu/g
UM4BV - Yeast - BAM Chapter 18	
Completion Date: 10/31/2019 **Method:** FDA BAM Chapter 18	
* Yeast	< 10 cfu/g
GFL07 - polychlorinated biphenyls (12 WHO PCB + 6 ICES PCB)	
Completion Date: 11/04/2019 **Method:** Internal	
* PCB 77	<2.93 pg/g
* PCB 81	<0.439 pg/g
* PCB 105	<6.34 pg/g
* PCB 114	<0.862 pg/g
* PCB 118	<22.8 pg/g
* PCB 123	<0.650 pg/g
* PCB 126	<0.407 pg/g
* PCB 156	<3.58 pg/g
* PCB 157	<0.667 pg/g
* PCB 167	<1.79 pg/g
* PCB 169	<1.95 pg/g
* PCB 189	<0.650 pg/g
* WHO(2005)-PCB TEQ (lower-bound)	ND
* WHO(2005)-PCB TEQ (medium-bound)	0.0504 pg/g
* WHO(2005)-PCB TEQ (upper-bound)	0.101 pg/g
* PCB 28	<0.163 ng/g
* PCB 52	<0.163 ng/g
* PCB 101	<0.163 ng/g
* PCB 138	<0.163 ng/g
* PCB 153	<0.163 ng/g
* PCB 180	<0.163 ng/g
* Total 6 ndl-PCB (lower-bound)	ND
* Total 6 ndl-PCB (medium-bound)	0.488 ng/g
* Total 6 ndl-PCB (upper-bound)	0.976 ng/g
UMDTC - Salmonella - AOAC-RI 121501	
Completion Date: 10/31/2019 **Method:** AOAC-RI 121501	
* Salmonella	Not Detected per 25 g

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AR-19-QA-078737-06

REPORT OF ANALYSIS

This analytical report supersedes AR-19-QA-078737-05.

Test Results	Result
UMHBM - Staphylococcus aureus - BAM Chapter 12	
Completion Date: 10/31/2019 **Method:** BAM Chapter 12	
* Staphylococcus aureus	< 10 cfu/g
GFTE1 - TEQ-Totals WHO-PCDD/F and PCB	
Completion Date: 11/04/2019 **Method:** Internal	
* WHO(2005)-PCDD/F+PCB TEQ (lower-bound)	ND
* WHO(2005)-PCDD/F+PCB TEQ (medium-bound)	0.134 pg/g
* WHO(2005)-PCDD/F+PCB TEQ (upper-bound)	0.268 pg/g

**This is not covered by our current A2LA accreditation.*

Respectfully Submitted,
Eurofins Central Analytical Laboratories

Victoria Siegel, Analytical Service Manager

Results shown in this report relate solely to the item submitted for analysis.
Uncertainty can be obtained upon request.

ACCREDITED TESTING CERT #2993-01

Any opinions/interpretations expressed on the Report of Analysis are outside the scope of this lab's A2LA accreditation.

EXHIBIT 1

Expert Panel Report

OPINION OF A GRAS PANEL ON THE SAFETY AND GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF DHA-ALGAL OIL FOR USE AS AN INGREDIENT IN HUMAN FOOD

Introduction

An independent panel of experts (GRAS Panel), qualified by scientific training and experience to evaluate the safety of food and food ingredients, was requested by Mara Renewables Corporation (Mara) to determine the safety and Generally Recognized as Safe (GRAS) status of the use of DHA-algal oil for use in food for human consumption. The DHA-algal oil produced using *Schizochytrium* sp. G3 is intended for use as a direct food ingredient in foods, to increase the dietary intake of the omega-3 fatty acid DHA. The DHA-algal oil ingredient is manufactured in accordance with current Good Manufacturing Practice (cGMP) and meets the proposed specifications.

A detailed review based on the existing scientific literature (through December 2019) on the safety of the DHA-algal oil produced using *Schizochytrium* sp. G3 was conducted by ToxStrategies, Inc. (ToxStrategies) and is summarized in the attached dossier. The GRAS Panel members reviewed the dossier prepared by ToxStrategies and other pertinent information and convened on February 10, 2020 via teleconference. Based on their independent, critical evaluation of all of the available information, the GRAS Panel unanimously concluded that the intended uses and use levels described herein for Mara's DHA-algal oil ingredient, meeting appropriate food-grade specifications as described in the supporting dossier (**GRAS Determination of DHA-Algal Oil for Use in Foods**) and manufactured according to cGMP, is safe, suitable, and GRAS based on scientific procedures. A summary of the basis for the GRAS Panel's conclusion is provided below.

Summary and Basis for GRAS Determination

Description

The DHA product that is the subject of this GRAS determination is a liquid, white-to-orange oil that is extracted and refined from the wild-type heterotrophic microalgae *Schizochytrium* sp. G3 (hereinafter referred to as G3). It is a mixture of triglycerides containing mostly polyunsaturated fatty acids (PUFA) in which the predominant fatty acid (>35%) is DHA.

Manufacturing Process

The DHA-algal oil, which is rich in polyunsaturated fatty acids (PUFA), is produced by a heterotrophic fermentation process with a single cell marine microalgae of the genus *Schizochytrium*, in particular G3. The fermentation process uses a medium containing carbon and nitrogen sources, bulk and trace mineral nutrients, and vitamins. Once fermentation is complete (i.e., as determined by carbon usage, cell growth, oil synthesis activity, and oil fatty acid profile), the crude oil that accumulates intracellularly is

recovered from the fermentation broth via an aqueous extraction process. To release the oil from the cells, the cell wall must be disrupted. In the cell wall disruption process, the fermentation broth is pH-adjusted with sodium hydroxide and hydrolyzed enzymatically. As a result, no intact algae remain in the oil. Following recovery of the crude algal oil, the following refining steps are completed: fractionation/winterization (optional), degumming/alkali refining (optional), bleaching, and deodorization.

Analytical (chemical and microbiological) results for Mara's DHA-algal oil product confirm that the finished product meets the proposed specifications as demonstrated by the consistency of production, the lack of impurities/contaminants (e.g., heavy metals, microbiological and algal toxins), and its stability under accelerated storage conditions over an 8-week period.

All of the fatty acids detected in the DHA-algal oil are well-known components of the human diet and found in both animal and vegetable food sources. The major fatty acids are DHA, myristic acid, palmitic acid, and docosapentaenoic acid. The proposed DHA oil is similar to other commercially available edible oils. Similarly, the detected sterols are also present in the human diet from vegetable and animal food sources such as common edible oils. Cholesterol levels as a percentage of total sterols were higher than comparable algal oils. However, the total sterol intake from the DHA-algal oil would be minimal. Additionally, the sterol profile of the proposed DHA-algal oil is similar to that found in other algal oils and fish oils that are currently used in food including infant formula.

History of Use

DHA-rich oils from numerous sources including microalgae are considered GRAS for use in food for human consumption, including infant formula (FDA, 2001, 2004, 2006, 2010, 2011a,b, 2014a,b, 2017, 2018a–d, 2019a–c). One other GRAS notification (GRN 862) for DHA-rich oil from microalgae is pending (FDA, 2019d). Sources of the oils include *Schizochytrium* sp., *Ulkenia* sp. SAM2179, *Chlorella protothecoides* strain S106, and *Prototheca moriformis* strain S2532. In addition, FDA has approved other sources of DHA for use in human food and/or infant formula, such as menhaden and fish oils (FDA, 2008a).

As noted for menhaden oil (21 CFR 184.1472) and other sources of DHA and/or EPA, FDA has determined that these oils may be used at a level that provides a total intake of DHA and/or EPA up to 3.0 grams per day. A review of previous GRAS notifications indicates that suppliers of DHA and EPA products, as well as their GRAS expert panels, have generally recommended a maximum limit of 1.5 grams of DHA or EPA per day when combined together. The maximum levels of use were designed to ensure that the combined daily intake of the two fatty acid components (i.e., EPA and DHA) would not exceed 3 grams per person per day. FDA has concurred with such an approach, providing "no questions" letters regarding such proposed food uses and associated intakes. In addition, the proposed food uses for this Mara DHA-rich algal oil product are identical to the uses for other GRAS-notified DHA and/or EPA products.

Intended Use and Intake Assessment

DHA-algal oil is intended for use as a direct food ingredient, except for in infant formula, to increase the dietary intake of the omega-3 fatty acid DHA. In the event that a manufacturer blends this Mara DHA-rich algal oil with another oil that is a source of DHA and/or EPA, such a mixture would be appropriate (in meeting FDA's 3.0-gram-per-day limit as described above), provided that (1) the DHA-rich algal oil is used at a level that would not result in an exposure of more than 1.5 grams of DHA per 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 grams per person per day. Because the proposed DHA algal oil contains approximately 50% DHA, compared to about 20% combined DHA and EPA in menhaden oil, the use levels need to be reduced to 20% of the menhaden oil levels to account for the 50% use level for DHA only, and the difference in concentration of DHA in the proposed algal oil (approximately 50%) compared to the concentration of EPA and DHA in menhaden oil (20%). In summary, the use levels of this Mara DHA-algal oil will be adjusted as necessary to provide no more than 1.5 g DHA per person per day for the food categories listed in 21 CFR 184.1472 (menhaden oil).

Safety Data

DHA is an important component of most cell membranes and tissues. DHA and DHA-algal oils are currently marketed for use in food, dietary supplements, and infant formula for human consumption. The Mara DHA-algal oil from *Schizochytrium* sp. G3 has a lipid (fatty acid) profile similar to that of currently marketed DHA from *Schizochytrium* sp., including T18 (GRN 677; FDA, 2017). Regulatory authorities have reviewed the safety of DHA and DHA-algal oils and found their use to be safe in human food, including infant formula. Numerous studies and publications support the safety of DHA and DHA-algal oils, including *in vitro* studies, *in vivo* animal studies, and clinical studies in humans. The most relevant studies on DHA including acute and subchronic toxicity, reproductive and developmental toxicity, mutagenicity and genotoxicity, chronic toxicity, and irritation/sensitization, along with clinical and epidemiological studies, all were summarized and reviewed as part of Mara's GRN 677 Notification for DHA algal oil from *Schizochytrium* sp. T18, as well as numerous other GRNs listed in the attached GRAS dossier. Kroes et al. (2003) reviewed and summarized the well understood metabolic fate of dietary DHA, which is similar to other dietary fatty acids. The published data, as well as reviews conducted by regulatory authorities, support the conclusion that Mara's DHA-rich algal oil produced using *Schizochytrium* sp. G3 is safe for use in food.

General Recognition of the Safety of DHA-Algal Oil from *Schizochytrium* sp. G3

The intended use of a DHA-rich algal oil has been determined to be safe through scientific procedures as set forth in 21 CFR § 170.3(b), thus satisfying the so-called "technical" element of the GRAS determination, and this conclusion is based on the following:

- The DHA product that is the subject of this GRAS determination is an extracted and refined oil from the wild-type heterotrophic microalgae *Schizochytrium* sp. G3. It is a mixture of triglycerides containing mostly PUFA, in which the predominant fatty acid (>35%) is DHA. The DHA manufacturing process starts with fermentation followed by refining of the crude DHA-algal oil isolated from the fermentation process. The DHA-algal oil product is manufactured consistent with cGMP for food (21 CFR Part 110 and Part 117 Subpart B). The raw materials and processing aids used in the manufacturing process are food grade and/or commonly used in fermentation and food manufacturing processes.

- The possible presence of microalgae toxins from *Schizochytrium* sp. has been addressed previously as part of a substantial equivalence submission (ONC, 2011), in GRAS Notification (GRN) No. 553 (FDA, 2014a), and as part of this GRAS notification. Toxin production is unlikely, because there are no known reports of toxin production by thraustochytrids, of which *Schizochytrium* is a member (ONC, 2011; Hammond et al., 2002). In addition, *Schizochytrium* sp. G3 oil and algal biomass were screened for the presence of toxins, including azaspiracids, pectenotoxins, okadaic acid, yessotoxins, and diarrhetic shellfish toxins (DSP), none of which were detected.

- There is common knowledge of a long history of human consumption of DHA from food and foods containing added DHA, from infant formula, and from other products such as dietary supplements. It will be added to food to supplement the dietary intake of the omega-3 fatty acid DHA.

- Literature searches did not identify safety/toxicity concerns related to any individual fatty acid or their ratios in the proposed DHA-algal oil. The *Schizochytrium* sp. G3 produced DHA oil is similar in fatty acid profile to T18 algal oil and other commercially available edible oils incorporated in foods and infant formulas, and to other algal oils and fish oils (e.g., krill oil) that are currently used in food and/or infant formula.

- The proposed uses of the DHA-algal oil product from *Schizochytrium* sp. G3 in food are identical to the approved uses for other GRAS-notified DHA and/or EPA products. As with the use of menhaden oil, the maximum levels of use were designed to ensure that the combined daily intake of the two fatty acid components (i.e., EPA and DHA) would not exceed 3 grams per person per day. In the event that a manufacturer blends Mara's DHA-rich algal oil or powder with another oil that is a source of DHA and/or EPA, such a mixture would meet FDA's daily exposure criteria, provided that (1) the DHA-rich algal oil is used at a level that would not result in an exposure of more than 1.5 grams of DHA per 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 grams per person per day. Because the proposed DHA-algal oil contains approximately 50% DHA, compared to about 20% combined EPA and DHA in menhaden oil, the use levels need to be reduced to 20% (as described in Table 11 of the dossier) of the menhaden oil use levels to account for the 50% percent

use level for DHA only, and the difference in concentration of DHA in the proposed algal oil (50%) compared to the concentration of EPA and DHA in menhaden oil (20%).

- DHA-rich oils from numerous sources, including microalgae, are considered GRAS for use in food for human consumption, including infant formula (FDA 2001, 2004, 2006, 2010, 2011a,b, 2014a, b, 2017, 2018a–d, 2019a–c). One other GRAS notification (GRN 862) for DHA-rich oil from microalgae is pending (FDA, 2019d). Sources of the oils include *Schizochytrium* sp., *Ulkenia* sp. SAM2179, *Chlorella protothecoides* strain S106, and *Prototheca moriformis* strain S2532. In addition, FDA has approved other sources of DHA for use in human food and/or infant formula, such as menhaden and fish oils (FDA, 2008a).

- Toxicity testing has been conducted with Mara's DHA-rich algal oil product from *Schizochytrium* sp. T18 (essentially equivalent to DHA from *Schizochytrium* sp. G3) and includes acute and subchronic toxicity studies, a battery of genotoxicity studies, and developmental and reproductive toxicity studies. In all of the studies, no evidence of toxicity was noted at the highest dose levels tested.

- The body of publicly available scientific literature on the consumption and safety of DHA and DHA-algal oil ingredients from both clinical studies in humans as well as animals is extensive and is sufficient to support the safety and GRAS status of the DHA-algal oil product from *Schizochytrium* sp. G 3.

- Because this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

Conclusions of the GRAS Panel

We, the undersigned independent, qualified members of the GRAS Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Mara's DHA-algal oil as an ingredient in foods. We unanimously conclude that the intended use of Mara's DHA-algal oil, produced consistent with current good manufacturing practice (cGMP) and meeting the appropriate food-grade specifications, as presented in the supporting dossier "GRAS Determination of DHA-Algal Oil for Use in Foods", is safe.

We, the members of the GRAS Panel, further unanimously conclude that the intended uses and use levels of Mara's DHA-algal oil in foods for human consumption, produced consistent with current good manufacturing practice (cGMP) and meeting the appropriate food-grade specifications as presented in the supporting dossier is Generally Recognized as Safe (GRAS) based on scientific procedures under the conditions of intended use in conventional foods specified herein.

It is our professional opinion that other qualified experts critically evaluating the same information would concur with this conclusion.

_____ _____

Paul Damian, Ph.D., M.P.H., DABT, ERT — Date
Principal
Damian Applied Toxicology, LLC

_____ _____

Carol A. Knight, Ph.D. — Date
Consultant
Knight International

_____ _____

Stanley M. Tarka, Jr., Ph.D., Fellow, ATS — Date
The Tarka Group, Inc.
The Pennsylvania State University, College of Medicine

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[redacted]

Paul Damian, Ph.D., M.P.H., DABT, ERT
Principal
Damian Applied Toxicology, LLC

2/10/2020
Date

Carol A. Knight, Ph.D.
Consultant
Knight International

Date

Stanley M. Tarka, Jr., Ph.D., Fellow, ATS
The Tarka Group, Inc.
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Principal
Damian Applied Toxicology, LLC

Date

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Knight International

Feb 10, 2020
Date

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The Tarka Group, Inc.
The Pennsylvania State University, College of Medicine

Date

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Carol A. Knight, Ph.D.
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The Pennsylvania State University, College of Medicine

10 February 2020
Date

References

Kroes R, Schaefer EJ, Squire RA, Williams GM. 2003. A review of the safety of DHA45-oil. Food Chem Toxicol 41:1443–1446.

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U.S. Food and Drug Administration (FDA). 2004. GRN137: GRAS Notification for DHA Algal Oil Derived from *Schizochytrium* sp.

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U.S. Food and Drug Administration (FDA). 2018b. GRN732: GRAS Notice for docosahexaenoic acid oil produced in *Schizochytrium* sp.

U.S. Food and Drug Administration (FDA). 2018c. GRN776: GRAS Notice for algal oil (35% docosahexaenoic acid) from *Schizochytrium* sp. FCC-1324.

U.S. Food and Drug Administration (FDA). 2018d. GRN777: GRAS Notice for algal oil (55% docosahexaenoic acid) from *Schizochytrium* sp. FCC-1324.

U.S. Food and Drug Administration (FDA). 2019a. GRN836: GRAS Notice for algal oil (50-60% docosahexaenoic acid) from *Schizochytrium* sp. HS01.

U.S. Food and Drug Administration (FDA). 2019b. GRN843: GRAS Notice for algal oil (35% docosahexaenoic acid) from *Schizochytrium* sp. strain FCC-1324.

U.S. Food and Drug Administration (FDA). 2019c. GRN844: GRAS Notice for algal oil (55% docosahexaenoic acid) from *Schizochytrium* sp. strain FCC-3204.

U.S. Food and Drug Administration (FDA). 2019d. GRN862: GRAS Notice for algal oil (40% docosahexaenoic acid) from *Schizochytrium* sp. strain ONC-T18.

U.S. Food Standards Agency. 2012. Opinion on the substantial equivalence of a DHA rich oil from microalgae. March 16.

From:	Don Schmitt
To:	Downey, Jason
Cc:	James Peach
Subject:	Re: GRN 913 (Mara G3 algal oil) Requests for additional information
Date:	Friday, June 26, 2020 4:23:15 PM
Attachments:	image002.png Mara FDA responses GRN 913 062920.pdf

Hi Jason,

Here are Mara's responses to FDA's questions regarding GRN 913.

Regards,

Don

Donald F. Schmitt, M.P.H.
Senior Managing Scientist

ToxStrategies, Inc.
739 Thornapple Drive
Naperville, IL 60540
phone: 630.352.0303
email: dschmitt@toxstrategies.com

From: "Downey, Jason" <Jason.Downey@fda.hhs.gov>
Date: Monday, June 15, 2020 at 2:50 PM
To: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Subject: GRN 913 (Mara G3 algal oil) Requests for additional information

Hi Don,

During our review of GRN 913, which you submitted on behalf of Mara Renewables Corporation for use of G3 algal oil in menhaden oil food categories, we noted nine requests for additional information, which are listed below. Please provide responses to these requests within **10 business days**. If you are unable to complete the response within that time frame, please contact me to discuss further options. If you have questions or need further clarification, please feel free to contact me. Thank you in advance for you attention to our comments.

Regards,

Jason

Jason Downey, PhD
Regulatory Review Scientist
Division of Food Ingredients
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
U.S. Food and Drug Administration
jason.downey@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

GRN 913 Questions to the Notifier

1. Please compare the molecular identity between *Aurantiochytrium* sp. strains G3 and ONC-T18 (e.g., ribosomal RNA sequence identity or any other markers) so that the studies cited in the notice that were performed with strain ONC-T18 can be used to justify the safety of strain G3.
2. Please indicate whether *Aurantiochytrium* sp. strain G3 is non-pathogenic.
3. Please indicate whether the analytical methods used in this notice are validated for their intended use.
4. In table 1 on page 12 of the notice, Mara lists cobalt (II) chloride as a component of the fermentation medium used in the manufacture of Mara's algal oil. Per 21 CFR 189.120, food containing added cobaltous salts, including cobalt (II) chloride, is deemed adulterated. Please discuss the potential presence of cobalt in the final product and provide analytical data from five non-consecutive batches indicating that cobalt is not present in the final product.
5. Certificates of analysis (COAs) were not provided for the fat and carbohydrate results presented in table 5 and for the molybdenum results presented in table 8. Please provide these COAs.
6. Please provide a statement on the intended shelf-life of Mara's algal oil. On page 24

of the notice, Mara notes that a 12-month stability study is in progress. Please provide an update on the 12-month stability study including interim results if available.

7. In table 11 on page 27, Mara lists meat and poultry use levels of 1.0% and 0.6%, respectively. On page 8, Mara lists meat and poultry use levels of 1.45% and 0.87%, respectively. Please clarify the maximum intended use levels of algal oil in meat and poultry products.

8. Mara states that the maximum dietary exposures to DHA and the combination of DHA and EPA from the intended uses of Mara's G3 algal oil are 1.5 g DHA/person (p)/day (d) and 3.0 g DHA+EPA/p/d, respectively. Mara also states that cumulative exposure to the combination of DHA and EPA will not exceed 3.0 g/p/d.

    a. Please clarify whether these limits are based on the mean or 90^{th} percentile exposure.

    b. Please explain how Mara will ensure that the cumulative dietary exposure to DHA and to the combination of DHA and EPA will not exceed 1.5 g DHA/p/d and 3.0 g DHA+EPA/p/d, respectively.

    c. Please state whether Mara intends for its use of G3 algal oil to be substitutional for existing uses of other DHA-containing oils. If these uses are not substitutional, please address the cumulative dietary exposure to DHA from all uses of algal oil.

9. On pages 29, 39, 41, and 89, Mara refers to a powder formulation of their algal oil, which is not presented in the manufacturing section of the notice. For the administrative record, please provide a statement that corrects these references.

Responses to Questions/Comments Regarding GRN 000913:

Question 1. Please compare the molecular identity between *Aurantiochytrium* sp. strains G3 and ONC-T18 (e.g., ribosomal RNA sequence identity or any other markers) so that the studies cited in the notice that were performed with strain ONC-T18 can be used to justify the safety of strain G3.

Response: 18S ribosomal sequencing analysis of G3 and ONC-T18 demonstrates 90% similarity, proof of a high degree of similarity and justification for use of ONC-T18 safety studies to support the safety of the G3 strain. Sequencing data is attached.

Question 2. Please indicate whether *Aurantiochytrium* sp. strain G3 is non-pathogenic.

Response: *Aurantiochytrium* (*Schizochytrium*) sp. strain G3 is non-pathogenic.

Question 3. Please indicate whether the analytical methods used in this notice are validated for their intended use.

Response: The analytical methods used in GRN 913 are validated for their intended use.

Question 4. In table 1 on page 12 of the notice, Mara lists cobalt (II) chloride as a component of the fermentation medium used in the manufacture of Mara's algal oil. Per 21 CFR 189.120, food containing added cobaltous salts, including cobalt (II) chloride, is deemed adulterated. Please discuss the potential presence of cobalt in the final product and provide analytical data from five non-consecutive batches indicating that cobalt is not present in the final product.

Response: Please see the attached analytical data for the cited batches. The results were inadvertently not included in the original GRN submission but do demonstrate that cobalt is not present in the final product.

Question 5. Certificates of analysis (COAs) were not provided for the fat and carbohydrate results presented in table 5 and for the molybdenum results presented in table 8. Please provide these COAs.

Response: COAs for fat and carbohydrate as well as molybdenum are attached. They were inadvertently not included in the original GRN submission.

Question 6. Please provide a statement on the intended shelf-life of Mara's algal oil. On page 24 of the notice, Mara notes that a 12-month stability study is in progress. Please provide an update on the 12-month stability study including interim results if available.

Response: Updated 12-week accelerated stability and 8-month stability data are attached.

Question 7. In table 11 on page 27, Mara lists meat and poultry use levels of 1.0% and 0.6%, respectively. On page 8, Mara lists meat and poultry use levels of 1.45% and 0.87%, respectively. Please clarify the maximum intended use levels of algal oil in meat and poultry products.

Response: Based on the USDA's safe and suitable list, DHA may be used as an alternative edible oil in the production of various meat and poultry products at a use level not to exceed 1.45 percent by weight of the product formulation for meat products and 0.87 percent by weight of the product formulation for poultry products. Page 8 should state use levels of 1.0% and 0.6% for meat and poultry, respectively. As stated in GRN 913 (p. 26), "Because the proposed DHA algal oil contains approximately 50% DHA, compared to about 20% combined DHA and EPA in menhaden oil, the use levels need to be reduced to 20% of the menhaden oil levels to account for the 50% use level for DHA only, and the difference in concentration of DHA in the proposed algal oil (approximately 50%) compared to the concentration of EPA and DHA in menhaden oil (20%)."

Question 8. Mara states that the maximum dietary exposures to DHA and the combination of DHA and EPA from the intended uses of Mara's G3 algal oil are 1.5 g DHA/person (p)/day (d) and 3.0 g DHA+EPA/p/d, respectively. Mara also states that cumulative exposure to the combination of DHA and EPA will not exceed 3.0 g/p/d.

a. Please clarify whether these limits are based on the mean or 90th percentile exposure.

b. Please explain how Mara will ensure that the cumulative dietary exposure to DHA and to the combination of DHA and EPA will not exceed 1.5 g DHA/p/d and 3.0 g DHA+EPA/p/d, respectively.

c. Please state whether Mara intends for its use of G3 algal oil to be substitutional for existing uses of other DHA-containing oils. If these uses are not substitutional, please address the cumulative dietary exposure to DHA from all uses of algal oil.

Response:

a. The use of Mara's G3 DHA algal oil is substitutional for existing uses of DHA-containing oils. Its maximum levels of use in food are based on the maximum approved use levels of menhaden oil in food (21 CFR 184.1472) and the percent DHA in the proposed algal oil product. As stated in the Federal Register Volume 62, Number 108 (Thursday, June 5, 1997), "In September 1993, the petitioner amended the petition to include maximum use levels for menhaden oil in various food categories. Based on these levels, FDA estimated that the mean exposure to EPA and DHA from the use of menhaden oil in all food categories would be 2.8 g/p/d. Based on this evaluation, the agency finds that the use of menhaden oil as a direct food ingredient is safe, provided that daily intakes of EPA and DHA from menhaden oil do not exceed 3 g/p/d. As noted in section VI of this document, the petitioned uses of menhaden oil incorporate maximum use levels for menhaden oil in specific food categories to ensure that daily intakes of EPA and DHA from menhaden oil do not exceed 3 g/p/d."

b. The food use levels of Mara's DHA algal oil are outlined in Table 10 of GRN 913 and are based on the maximum approved use levels of menhaden oil and the DHA contained therein. Mara does not manufacture food, but only the DHA algal oil ingredient. As with the use of menhaden oil and all other DHA ingredients, they may be used in food within the specific limitations in 21 CRR 184.1472 (and the percent DHA in the ingredients) to ensure that total intake of eicosapentaenoic acid or docosahexaenoic acid does not exceed 3.0 grams/person/day. Mara does not manufacture foods including DHA; the responsibility for the appropriate addition

of the DHA algal oil ingredient in specific categories of food lies with the food product manufacturer in accordance with the maximum levels specified in GRN 913.

c. The use of Mara's G3 DHA algal oil is substitutional for existing uses of DHA-containing oils as described in GRN 913. Therefore, its use in food will not result in an increase in the daily intake of DHA.

Question 9. On pages 29, 39, 41, and 89, Mara refers to a powder formulation of their algal oil, which is not presented in the manufacturing section of the notice. For the administrative record, please provide a statement that corrects these references.

Response: Reference to a powder formulation was in error and GRN 913 does not include a powder form of the product.

Question 1 Attachments

G3

CAACCTGGTTGAtCCTGCCAGTAGTCATATGCTCGTCTCAAAGATTAAGCCATGCATGTGTAAGTATAAGCGATTGT
ACTGTGAGACTGCGAACGGCTCATTATATCAGTAATAATTTCTTCGGTAGTTTCTTTTATATGGATACCTGCAGTAA
TTCTGGAAATAATACATGCTGTAAGAGCCCTGTATGGGGCTGCACTTATTAGATTGAAGCCGATTTTATTGGTGAA
TCATGATAATTGAGCAGATTGACTTTTTAGTCGATGAATCGTTTGAGTTTCTGCCCCATCAGTTGTCGACGGTAGTG
TATTGGACTACGGTGACTATAACGGGTGACGGAGAGTTAGGGCTCGACTCCGGAGAGGGAGCCTGAGAGACGGCT
ACCATATCCAAGGATAGCAGCAGGCGCGTAAATTACCCACTGTGGACTCCACGAGGTAGTGACGAGAAATATCGA
TGCGAAGCGTGTATGCGTTTTGCTATCGGAATGAGAGCAATGTAAAACCCTCATCGAGGATCAACTGGAGGGCAA
GTCTGGTGCCAGCAGCCGCGGTAATTCCAGCTCCAGAAGCATATGCTAAAGTTGTTGCAGTTAAAAAGCTCGTAGT
TGAATTTCTGGCATGGGCGACCGGTGCTTTCCCTGAATGGGGATTGATTGTCTGTGTTGCCTTGGCCATCTTTTTCTT
TTCTTTATTGATGAGAAATCTTTCACTGTAATCAAAGCAGAGTGTTCCAAGCAGGTCGTATGACCGGTATGTTTATT
ATGGGATGATAAGATAGGACTTGGGTGCTATTTTGTTGGTTTGCACGCCTGAGTAATGGTTAATAGGAACAGTTGG
GGGTATTCGTATTTAGGAGCTAGAGGTGAAATTCTTGGATTTCCGAAAGACGAACTAGAGCGAAGGCATTTACCA
AGCATGTTTTCATTAATCAAGAACGAAAGTCTGGGGATCGAAGATGATTAGATACCATCGTAGTCTAGACCGTAAA
CGATGCCAACTTGCGATTGTTGGGTGCTTTTTTATGGGCCTCAGCAGCAGCACATGAGAAATCAAAGTCTTTGGGT
TCCGGGGGGGAGTATGGTCGCAAGGCTGAAACTTAAAGGAATTGACGGAAGGGCACCACCAGGAGTGGAGCCTGC
GGCTTAATTTGACTCAACACGGGAAAACTTACCAGGTCCAGACATAGGTAGGATTGACAGATTGAGAGCTCTTTCA
TGATTCTATGGGTGGTGGTGCATGGCCGTTCTTAGTTGGTGGAGTGATTTGTCTGGTTAATTCCGTTAACGAACGAG
ACCTCGGCCTACTAAATAGTGCGTGGTATGGCAACATAGTACGTTTTAACTTCTTAGAGGGACATGTCCGGTTTAC
GGGCAGGAAGTTCGAGGCAATAACAGGTCTGTGATGCCCTTAGATGCTCTGGGCCGCACGCGCGCTACACTGATG
GGTTCATCGGGTTTTAATTTCATTATTGGAATTGAGTGCTTGGTCGGAAGGCCTGGCTAATCCTTGGAACGCTCATC
GTGCTGGGGCTAGATTTTTGCAATTATTAATCTCCAACGAGGAATTCCTAGTAAACGCAAGTCATCAGCTTGCATT
GAATACGTCCCTGCCCTTTGTACACACCGCCCGTCGCACCTACCGATTGAACGGTCCGATGAAACCATGGGATGTT
TGTGTTTGGATTCATTTTTGGACATAGGCAGAACTCGGGTGAATCTTATTGTTTAGAGGAAGGTGAAGTCGTAACA
AGGTTTCCGTAG

T18

CAACCTGGTTGATCCTGCCAGTAGCCCTACGCTCGTCTCAAAGATTAAGCCATGCATGTGTAAGTATAAGCGATTA
TACTGTGAGACTGCGAACGGCTCATTATATCAGTTATGATTTCTTCGGTATTTTCTTTATATGGATACCTGCAGTAA
TTCTGGAATTAATACATGCTGAGAGGGCCCGACTGTTCGGGAGGGCCGCACTTATTAGAGTTGAAGCCAAGTAAG
ATGGTGAGTCATGATAATTGAGCAGATCGCTTGTTTGGAGCGATGAATCGTTTGAGTTTCTGCCCCATCAGTTGTCG
ACGGTAGTGTATTGGACTACGGTGACTATAACGGGTGACGGGGAGTTAGGGCTCGACTCCGGAGAGGGAGCCTGA
GAGACGGCTACCACATCCAAGGAAGGCAGCAGGCGCGTAAATTACCCAATGTGGACTCCACGAGGTAGTGACGA
GAAATATCAATGCGGGGCGCTTCGCGTCTTGCTATTGGAATGAGAGCAATGTAAAACCCTCATCGAGGATCAACTG
GAGGGCAAGTCTGGTGCCAGCAGCCGCGGTAATTCCAGCTCCAGAAGCGTATGCTAAAGTTGTTGCAGTTAAAAA
GCTCGTAGTTGAATTTCTGGCGCGGGAGCCCCGGTCTTTGCGCGACTGCGCTCTGTTTGCCGAGCGGCTCCTCTGCC
ATCCTCGCCTCTTTTTTTAGTGGCGTCGTTCACTGTAATTAAAGCAGAGTGTTCCAAGCAGGTCGTATGACCTGGAT
GTTTATTATGGGATGATCAGATAGGGCTCGGGTGCTATTTTGTTGGTTTGCACATCTGAGTAATGATGAATAGGAA
CAGTTGGGGGTATTCGTATTTAGGAGCTAGAGGTGAAATTCTTGGATTTCCGAAAGACGAACTACAGCGAAGGCA
TTTACCAAGCATGTTTTCATTAATCAAGAACGAAAGTCTGGGGATCGAAGATGATTAGATACCATCGTAGTCTAGA
CCGTAAACGATGCCGACTTGCGATTGCGGGGTGTTTGTATTGGACCCTCGCAGCAGCACATGAGAAATCAAAGTCT
TTGGGTTCCGGGGGGAGTATGGTCGCAAGGCTGAAACTTAAAGGAATTGACGGAAGGGCACCACCAGGAGTGGA
GCCTGCGGCTTAATTTGACTCAACACGGGAAAACTTACCAGGTCCAGACATAGGTAGGATTGACAGATTGAGAGC
TCTTTCTTGATTCTATGGGTGGTGGTGCATGGCCGTTCTTAGTTGGTGGAGTGATTTGTCTGGTTAATTCCGTTAAC
GAACGAGACCTCGGCCTACTAAATAGCGGTGGGTATGGCGACATACTTGCGTACGCTTCTTAGAGGGACATGTTCG
GTATACGAGCAGGAAGTTCGAGGCAATAACAGGTCTGTGATGCCCTTAGATGTTCTGGGCCGCACGCGCGCTACA
CTGATGGGTTCAACGGGTGGTCATCGTTGTTCGCAGCGAGGTGCTTTGCCGGAAGGCATGGCAAATCCTTTCaACG
CCCATCGTGCTGGGGCTAGATTTTTGCAATTATTAATCTCCAACGAGGAATTCCTAGTAAACGCAAGTCATCAGCT
TGCATTGAATACGTCCCTGCCCTTTGTACACACCGCCCGTCGCACCTACCGATTGAACGGTCCGATGAAACCATGG
GATGACCTTTTGAGCGTTTGTTCGCGAGGGGGGTCAGAACTCGGGTGAATCTTATTGTTTAGAGGAAGGTGAAGTC
GTAACAAGGTTTCCGTAGTGA

Question 4 and 5 Attachments

Report ID: 335056-IAS
Report Date: 06-Nov-19
Date Received: 30-Oct-19

CERTIFICATE OF ANALYSIS

for
Mara Renewables Corp
101 Research Drive
Dartmouth, NS B2Y 4T6

rpc
921 College Hill Rd
Fredericton NB
Canada E3B 6Z9
Tel: 506.452.1212
Fax: 506.452.0594
www.rpc.ca

Attention: Paula Mercer
Project #: Not Available

Analysis of Samples

RPC Sample ID:			335056-1	335056-1 Dup	335056-2	335056-3	335056-4	335056-5
Client Sample ID:			N-2-024-C-G3	Lab Duplicate	N-2-026-C-G3	N-2-022-R-G3	N-2-024-R-G3	N-2-026-R-G3
Date Sampled:			28-Oct-19	28-Oct-19	28-Oct-19	28-Oct-19	28-Oct-19	28-Oct-19
Analytes	**Units**	**RL**						
Cobalt	mg/kg	0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01
Lead	mg/kg	0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01
Molybdenum	mg/kg	0.02	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02
Strontium	mg/kg	0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1

This report relates only to the sample(s) and information provided to the laboratory.

RL = Reporting Limit

Ross Kean
Department Head
Inorganic Analytical Chemistry

METALS

Peter Crowhurst
Analytical Chemist
Inorganic Analytical Chemistry

CERTIFICATE OF ANALYSIS

for
Mara Renewables Corp
101 Research Drive
Dartmouth, NS B2Y 4T6

rpc
921 College Hill Rd
Fredericton NB
Canada E3B 6Z9
Tel: 506.452.1212
Fax: 506.452.0594
www.rpc.ca

General Report Comments

Portions of the samples were prepared by Microwave Assisted Digestion in nitric acid (SOP 4.M26).
The resulting solutions were analyzed for trace elements by ICP-MS (SOP 4.M01).
Mercury was analyzed by Cold Vapour AAS (SOP 4.M52 & SOP 4.M53).

Report ID: 335056-IAS
Report Date: 06-Nov-19
Date Received: 30-Oct-19

CERTIFICATE OF ANALYSIS

for

Mara Renewables Corp
101 Research Drive
Dartmouth, NS B2Y 4T6

Project #: Not Available

QA/QC Report

RPC Sample ID:			RB063336
Type:			Blank
Analytes	**Units**	**RL**	
Cobalt	mg/kg	0.01	< 0.01
Lead	mg/kg	0.01	< 0.01
Molybdenum	mg/kg	0.02	< 0.02
Strontium	mg/kg	0.1	< 0.1

Report ID: 339057-OAS
Report Date: 16-Dec-19
Date Received: 06-Dec-19

CERTIFICATE OF ANALYSIS

for
Mara Renewables Corp
101 Research Drive
Dartmouth, NS B2Y 4T6

rpc
921 College Hill Rd
Fredericton NB
Canada E3B 6Z9
Tel: 506.452.1212
Fax: 506.452.0594
www.rpc.ca

Attention: Paula Mercer
Project #: Not Available

Food Chemistry

RPC Sample ID:			339057-1	339057-2	339057-3
Client Sample ID:			N-2-022-R-G3	N-2-024-R-G3	N-2-026-R-G3
Date Sampled:			20-Sep-19	20-Sep-19	20-Sep-19
Matrix:					
Analytes	Units	RL			
Moisture	g/100g	0.30	< 0.30	< 0.30	< 0.30
Protein	g/100g	0.20	< 0.20	< 0.20	< 0.20
Fat (Acid Hydrolysis)	g/100g	0.50	101	102	101
Ash	g/100g	0.1	< 0.1	< 0.1	< 0.1
Carbohydrates	g/100g	0.1	< 0.1	< 0.1	< 0.1

This report relates only to the sample(s) and information provided to the laboratory.
RL = Reporting Limit

Bruce Phillips
Department Head
Organic Analytical Services

Jill Hay
Senior Food Chemistry Technician
Organic Analytical Services

Report ID: 339057-OAS
Report Date: 16-Dec-19
Date Received: 06-Dec-19

CERTIFICATE OF ANALYSIS

for
Mara Renewables Corp
101 Research Drive
Dartmouth, NS B2Y 4T6

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921 College Hill Rd
Fredericton NB
Canada E3B 6Z9
Tel: 506.452.1212
Fax: 506.452.0594
www.rpc.ca

Method Summary

OAS-FC06:Determination of Fat in Foods by Acid Hydrolysis (AOAC 948.15)
OAS-FC01:Determination of Moisture in Foods (AOCS Ca 2c-25)
OAS-FC04: Determination of Protein in Foods (AOAC 981.10)
OAS-FC02:Determination of Ash in Foods (AOAC 920.153)

COMMENTS

Report ID: 339057-OAS
Report Date: 16-Dec-19
Date Received: 06-Dec-19

CERTIFICATE OF ANALYSIS

for
Mara Renewables Corp
101 Research Drive
Dartmouth, NS B2Y 4T6

rpc
921 College Hill Rd
Fredericton NB
Canada E3B 6Z9
Tel: 506.452.1212
Fax: 506.452.0594
www.rpc.ca

Project #: Not Available

Summary of Date Analyzed

RPC Sample ID	**Analyzed**
339057-1	6-Dec-19
339057-2	6-Dec-19
339057-3	6-Dec-19

Question 6 Attachments

Refined Oil Lot N-2-022-R-G3

Frozen condition @ -18°C						
Property	Spec	Initial	Month 1	Month 4	Month 8	Month 12
PV	≤ 5 meq/kg	0.4	0.4	0.5	0.5	
pAV	NA	0.6	1.6	0.7	0.7	
Acid value (FFAV)	Max. 0.5%	0.11	0.07	0.11	0.14	
DHA %	Min. 35	55.7	55.4	55.3	56.3	

Ambient condition 22-25°C						
Property	Spec	Initial	Month 1	Month 4	Month 8	Month 12
PV	≤ 5 meq/kg	0.4	2.5	1.1	1.4	
pAV	NA	0.6	1.7	2.0	3.8	
Acid value (FFAV)	Max. 0.5%	0.11	0.1	0.1	0.14	
DHA %	Min. 35	55.7	55.6	55.2	56.3	

Accelerated condition 35°C						
Property	Spec	Initial	Week 1	Week 4	Week 8	Week 12
PV	≤ 5 meq/kg	0.4	2.0	0.9	1.1	0.3
pAV	NA	0.6	1.2	1.9	3.2	4.1
Acid value (FFAV)	Max. 0.5%	0.11	0.11	0.12	0.10	0.10
DHA %	Min. 35	55.7	55.9	55.4	55.8	56.2

Refined Oil Lot N-2-024-R-G3

Frozen condition @ -18°C						
Property	Spec	Initial	Month 1	Month 4	Month 8	Month 12
PV	≤ 5 meq/kg	0.7	1.3	1.5	2.1	
pAV	NA	1.1	1.5	1.5	1.2	
Acid value (FFAV)	Max. 0.5%	0.06	0.08	0.11	0.14	
DHA %	Min. 35	54.5	54.4	54.1	55.1	

Ambient condition 22-25°C						
Property	Spec	Initial	Month 1	Month 4	Month 8	Month 12
PV	≤ 5 meq/kg	0.7	3.4	1.8	2.6	
pAV	NA	1.1	3.0	2.4	3.7	
Acid value (FFAV)	Max. 0.5%	0.06	0.09	0.07	0.14	
DHA %	Min. 35	54.5	54.3	54.1	55.1	

Accelerated condition 35°C						
Property	Spec	Initial	Week 1	Week 4	Week 8	Week 12
PV	≤ 5 meq/kg	0.7	2.4	1.7	1.2	0.8
pAV	NA	1.1	2.0	2.4	3.1	3.7
Acid value (FFAV)	Max. 0.5%	0.06	0.11	0.10	0.09	0.10
DHA %	Min. 35	54.5	54.6	54.1	54.6	54.9

Refined Oil Lot N-2-026-R-G3

Frozen condition @ -18°C						
Property	Spec	Initial	Month 1	Month 4	Month 8	Month 12
PV	≤ 5 meq/kg	0.6	1.0	0.7	0.9	
pAV	NA	0.6	1.4	0.7	0.7	
Acid value (FFAV)	Max. 0.5%	0.08	0.09	0.07	0.14	
DHA %	Min. 35	59.5	59.4	59.2	60.2	

Ambient condition 22-25°C						
Property	Spec	Initial	Month 1	Month 4	Month 8	Month 12
PV	≤ 5 meq/kg	0.6	2.8	1.8	2.5	
pAV	NA	0.6	2.4	2.1	3.1	
Acid value (FFAV)	Max. 0.5%	0.08	0.09	0.10	0.14	
DHA %	Min. 35	59.5	59.5	59.1	60.3	

Accelerated condition 35°C						
Property	Spec	Initial	Week 1	Week 4	Week 8	Week 12
PV	≤ 5 meq/kg	0.6	1.8	1.7	1.8	1.5
pAV	NA	0.6	1.7	1.5	2.8	3.3
Acid value (FFAV)	Max. 0.5%	0.08	0.12	0.09	0.1	0.09
DHA %	Min. 35	59.5	59.6	59.2	59.6	59.9

From:	Don Schmitt
To:	Downey, Jason
Cc:	James Peach
Subject:	Re: GRN 913 (Mara"s algal oil)
Date:	Tuesday, July 28, 2020 2:47:23 PM
Attachments:	image002.png

Hi Jason,

Here is an updated statement on stability to go along with the tables previously provided.

Stability Statement:

Stability testing (accelerated conditions) has been conducted on three non-consecutive batches of DHA algal oil for 12 weeks. DHA algal oil is typically shipped and stored at 4°C, –4°C, or frozen (–25°C). The results of the accelerated stability study demonstrate the stability of the product over an 12-week period, equivalent to 12 months. The accelerated stability data, combined with the trends in the long term stability data (8-months), support the assertion that DHA algal oil will remain stable under ambient and frozen conditions for up to 12 months.

Please let me know if you have any further questions.

Best regards,

Don

Donald F. Schmitt, M.P.H.
Senior Managing Scientist

ToxStrategies, Inc.
739 Thornapple Drive
Naperville, IL 60540
phone: 630.352.0303
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From: "Downey, Jason" <Jason.Downey@fda.hhs.gov>
Date: Tuesday, July 28, 2020 at 9:30 AM
To: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Subject: RE: GRN 913 (Mara's algal oil)

RE: GRN 913 – Mara's DHA algal oil

Hi Don,
I hope all is well on your end.
In the amendment we received on June 26, 2020, Mara provided additional stability data for their algal oil but didn't comment on what the data show. The only statement that I have from the notifier regarding shelf life is in the original notice, which stated the algal oil is stable for at least 8 weeks based on accelerated stability studies. Because the notice is a description of Mara's own GRAS conclusion, the record should capture what Mara concludes from these additional data. Does Mara wish to provide an updated statement on stability in light of the additional stability data?
Feel free to give me a call if you have any questions.
Thanks!
Jason

Jason Downey, PhD
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240-402-9241
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From:	Don Schmitt
To:	Downey, Jason
Cc:	James Peach
Subject:	Re: GRN 913 - Question about reagent
Date:	Tuesday, September 1, 2020 12:29:22 PM
Attachments:	image002.png

Hi Jason,

Hope you are well.

Mara has just confirmed that it is low erucic acid rapeseed oil that they are referring to (aka canola oil).

Don

Donald F. Schmitt, M.P.H.
Senior Managing Scientist

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From: "Downey, Jason" <Jason.Downey@fda.hhs.gov>
Date: Tuesday, September 1, 2020 at 11:06 AM
To: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Subject: GRN 913 - Question about reagent

RE: GRN 913 – Mara's DHA Algal Oil

Hi Don,
We have a quick question about one of the reagents referenced in GRN 913:
On page 16 and in table 2, the notice says rapeseed oil could be used to standardize DHA content in the final oil. Table 2 also references 21 CFR 184.1555 for rapeseed oil. Can you confirm whether "rapeseed oil" as used in the notice refers to low erucic acid rapeseed oil, aka canola oil (§184.1555(c))? If not, can you provide non-confidential information about identity of the rapeseed oil used in the notice?
Thank you,
Jason

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