SWEDISH OATFIBER

April 15, 2020

Dr. Paulette Gaynor
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

Dear Dr. Gaynor

RE: GRAS Exemption Claim for Oat Oil PL40

In accordance with 21 CFR §170.225(c)(1) [Notice of a claim for exemption based on a Generally Recognized as Safe (GRAS) determination] published in the *Federal Register* [81 FR 54960 (17 August 2016], I am submitting one hard copy and one electronic copy (on CD), as the notifier [Swedish Oat Fiber, Båtafjordsvägen 12, SE-43263 BUA, Sweden], a Notice of the evaluation, on the basis of scientific procedures, that Oat Oil PL40, as defined in the enclosed documents and manufactured according to current Good Manufacturing Practices, is GRAS under specific conditions of use as an ingredient in food and beverages, and therefore, is exempt from the premarket approval requirements of the *Federal Food, Drug, and Cosmetic Act.* Information setting forth the basis for the GRAS evaluation, which includes detailed information on the notified substance and a summary of the basis for GRAS status, as well as a consensus opinion of an independent panel of experts in support of the safety of oat oil PL40 under the intended conditions of use, also are enclosed.
The enclosed electronic files for the Notice entitled, "GRAS Notice for Oat Oil PL40" were scanned for viruses prior to submission and are thus certified as being virus-free using Symantec Endpoint Protection version 12.1.5.
Should you have any questions or concerns regarding this GRAS Notice, please do not hesitate to contact me at any point during the review process so that we may provide a response in a timely manner.

Yours sincerely

[redacted]

Peo Crona
Company Manager
Swedish Oat Fiber

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GRAS NOTICE FOR OAT OIL PL40

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

SUBMITTED BY:
Swedish Oat Fiber
Båtafjordsvägen 12
SE-43263 BUA
Sweden

DATE:
15 April 2020

GRAS Notice for Oat Oil PL40

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GRAS Notice for Oat Oil PL40

Part 1. §170.225 Signed Statements and Certification

In accordance with 21 CFR §170 Subpart E consisting of §§170.203 through 170.285, Swedish Oat Fiber hereby informs the United States (U.S.) Food and Drug Administration (FDA) that the intended uses of oat oil PL40, as manufactured by Swedish Oat Fiber, in various conventional food and beverage products as described in Section 1.3 below, are not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on Swedish Oat Fiber's view that these notified uses of oat oil PL40 are Generally Recognized as Safe (GRAS). In addition, as a responsible official of Swedish Oat Fiber, the undersigned hereby certifies that all data and information presented in this notice represent a complete and balanced submission that is representative of the generally available literature. Swedish Oat Fiber considered all unfavorable, as well as favorable, information that is publicly available and/or known to Swedish Oat Fiber and that is pertinent to the evaluation of the safety and GRAS status of oat oil PL40 as a food ingredient for addition to food and beverage products as described herein.

Signed,

2020/04/15

Peo Crona
Company Manager
Swedish Oat Fiber

Date

1.1 Name and Address of Notifier

Peo Crona
Swedish Oat Fiber
Båtafjordsvägen 12
SE-43263 BUA Sweden

Telephone: +46704384869
Email: peo.crona@givudan.com

1.2 Common Name of Notified Substance

Oat oil; oat lipid extract; oat polar lipid extract; SWEOAT© Oil PL40; vegetable oil (oat)

1.3 Conditions of Use

Swedish Oat Fiber intends to market oat oil PL40 as a vegetable oil that will be a source of oat phospholipids and/or as an emulsifier. Oat oil PL40 may be used as a partial substitute or in addition to other fats and oils within food, up to its intended level of use in that product (see Table 1.3-1).

In addition to the use levels of oat oil PL40 in chocolate, which are dictated by the standard of identity, a summary of the food categories and use levels in which oat oil PL40 is intended for use is provided in Table 1.3-1 below. Food uses are organized according to 21 CFR §170.3 (U.S. FDA, 2019).

Table 1.3-1 Summary of the Individual Proposed Food Uses and Use Levels for Oat Oil in the U.S.

Food Category (21 CFR §170.3) (U.S. FDA, 2019)	Food Uses	Oat Oil Use Levels (g/100 g)
Baby Food	Baby food: Cereals	2.0
	Baby food: Dinners, Desserts, Fruits, Vegetables, or Soups	2.0
	Baby food: Ready-to-Eat Cereals, Cookies, Teething Biscuits, and Toasts	2.0
Baked Goods and Baking Mixes	Pan or Flat Bread Product	2.0
Beverages and Beverage Bases	Cocoa and/or Malted Beverages	2.0
	Flavored or Carbonated Waters	0.8
	Non-Milk-Based Meal Replacement Beverages	2.0
	Protein Drinks	2.0
	Sport or Electrolyte Drinks, Fluid Replacement Drinks	0.2
Breakfast Cereals	Instant Hot Breakfast Cereals	2.0
	Ready-to-Eat Breakfast Cereals	2.0
Coffee and Tea	Combined Coffee and Whitener Products	2.0
	Specialty Coffee Drinks (Lattes, Cappuccinos, Mochas)	2.0
Dairy Product Analogs	Non-Dairy Based Ambient and Chilled Dessert *e.g.*, mousse	2.0
	Non-Dairy Culinary Cooking Creams Sauces	2.0
	Non-Dairy Milk, Cream, and Coffee/Tea Whiteners	2.0
Fats and Oils	Margarine, and Margarine-Like Spreads	2.0
	Mayonnaise and Mayonnaise-Type Dressings	2.0
	Oils	2.0
	Salad Dressings	2.0
Frozen Dairy Desserts	Frozen Yogurt (Frozen Yoghurt)	2.0
	Ice Cream	2.0
	Other Frozen Milk Desserts	2.0
Grain Products and Pastas	Cereal and Granola Bars	2.0
	Energy Bars or Protein Bars	2.0
	Meal Replacement Bars	2.0
Milk Products	Culinary Cooking Creams Sauces	2.0
	Dairy Based Chilled or Ambient Dessert *e.g.*, mousse	2.0
	Flavored Milk, Milk Drinks, and Mixes	2.0
	Milk Shakes	2.0
	Milk-Based Meal Replacements	2.0
	Nutritional Supplement Meal Replacements	2.0
	Plain or Flavored Yogurt (Yoghurt)	2.0
Plant Protein Products	Meat Analogs	2.0
Snack Foods	Extruded and/or Expanded Materials for Humans for Example Extruded Snacks	2.0

Table 1.3-1 Summary of the Individual Proposed Food Uses and Use Levels for Oat Oil in the U.S.

Food Category (21 CFR §170.3) (U.S. FDA, 2019)	Food Uses	Oat Oil Use Levels (g/100 g)
Soft Candy	Chocolate[a]	2.0
	Nougat and Toffees	2.0

CFR = Code of Federal Regulations; U.S. = United States.

[a] In standardized chocolate oat oil is intended to be used only as an emulsifier due to the limitations on the types of optional additives permitted under Title 21 §163 of the CFR. In sweet chocolate, milk chocolate, buttermilk chocolate, skim milk chocolate, and mixed dairy products, the total combined emulsifying agent content may not exceed 1.0% by weight (U.S. FDA, 2019). Additionally, emulsifying agents may not exceed a total of 1.5% by weight in white chocolate (U.S. FDA, 2019). Oat oil PL40 is not intended to be used under the U.S. standard of identity for chocolate for any purpose outside of emulsification.

1.4 Basis for GRAS

Pursuant to 21 CFR §170.30 (a)(b) of the Code of Federal Regulations (CFR) (U.S. FDA, 2019), Swedish Oat Fiber has concluded that the intended uses of oat oil PL40 as described in Section 1.3 are GRAS on the basis of scientific procedures.

1.5 Availability of Information

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

Swedish Oat Fiber
Båtafjordsvägen 12
SE-43263 BUA Sweden

Should the FDA have any questions or additional information requests regarding this Notice, Swedish Oat Fiber will supply these data and information upon request.

1.6 Freedom of Information Act, 5 U.S.C. 552

It is Swedish Oat Fiber's view that all data and information presented in Parts 2 through 7 of this Notice do not contain any trade secret, commercial, or financial information that is privileged or confidential, and therefore, all data and information presented herein are not exempted from the Freedom of Information Act, 5 U.S.C. 552.

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

2.1 Identity

The ingredient that is the subject of this GRAS Notice is an extract from food-grade oat grain seeds of the *Avena sativa* (*A. sativa*) plant. The concentration of total lipid in the oat grain seeds is approximately 8.3%, of which 21% of the oat oil (1.7% of the oat kernel flour on a dry weight basis) is polar lipids (glycolipids and phospholipids) (Doehlert *et al.*, 2010). The oat varieties used in Sweden are cultivated through traditional breeding practices to thrive in the Nordic climate. Oats can be farmed on all types of soil and in Sweden they are planted in the spring for early autumn harvest.

Oat oil PL40 (Chemical Abstract Services Registry Number 84012-26-0) is a yellow-brown oil with a typical moisture content of 2% or less and an acid value of 30 mg KOH/g or less. Oat oil PL40 consists of 2 primary classes of lipids: triglycerides (neutral lipids), and polar lipids, the latter of which is further subdivided into phospholipids (phosphatidylcholine, phosphatidylglycerol, lyso-phosphatidylglycerol, n-acyl phosphatidylethanolamine, phosphatidylethanolamine, di-acyl-phosphatidylglycerol, and phosphatidic acid) and glycolipids [mono- and digalactosyldiacylglycerol (MGDG and DGDG, respectively), diacylglycerol-diacyl phosphatidylglycerol, and sterylglucoside]. All of these lipids are natural constituents of the oat grain and are not modified during manufacturing. Additional information on the identity and composition of oat oil PL40 is presented below; product specifications are provided in Table 2.3.1-1.

A representative lot of oat oil PL40 was analyzed by gas chromatography with flame ionization detector (GC-FID), and the fatty acid profile is presented in Table 2.1-1 below.

Table 2.1-1 Fatty Acid Profile of Oat Oil PL40

Fatty Acid (as % of total Fatty Acids)	Representative Batch Results (PL40FG-FG40-210915)
C 6:0 Caproic acid	< 0.1
C 8:0 Caprylic acid	< 0.1
C 10:0 Capric acid	< 0.1
C 12:0 Lauric acid	<0.1
C14:0 Myristic acid	0.2
C 14:1 Myristoleic acid	<0.1
C 15:0 Pentadecanoic acid	<0.1
C 15:1 n-5	<0.1
C 16:0 Palmitic acid	16.9
C 16:1 n-7 Palmitoleic acid	0.2
C 17:0 Margaric acid	<0.1
C 17:1 n-7 Heptadecenoic acid	<0.1
C 18:0 Stearic acid	1.7
C 18:1 n-9 Oleic acid	37.7
C 18:2 n-6 Linoleic acid	38.4
C 18:3 n-3 alpha-Linolenic acid	1.3
C 18:3 n-6 gamma-Linolenic acid	<0.1
C 18:4 n-3 Octadecatetraenoic acid	<0.1
C 20:0 Arachidic acid	0.1
C 20:1 n-9 Gadoleic acid	0.6

Table 2.1-1 Fatty Acid Profile of Oat Oil PL40

Fatty Acid (as % of total Fatty Acids)	Representative Batch Results (PL40FG-FG40-210915)
C 20:2 n-6 Eicosadien acid	<0.1
C 20:3 n-6	<0.1
C 20:3 n-3	<0.1
C 20:4 n-6 Arachidonic acid	<0.1
C 20:4 n-3	<0.1
C 20:5 n-3 Eicosapentaenoic acid	<0.1
C 22:0 Behenic acid	<0.1
C 22:1	0.2
C 22:2 n-6 Docosadienoic acid	0.1
C 22:4 n-6	<0.1
C 22:5 n-6	<0.1
C 22:5 n-3 Docosapentaenoic acid	<0.1
C 22:6 n-3 Docosahexaenoic acid	<0.1
C 24:0 Lignoceric acid	<0.1
C 24:1 n-9 Tetracosenoic acid	<0.1
Saturated fatty acids	**19.2**
Mono-unsaturated fatty acids	**38.7**
Polyunsaturated fatty acids	**39.9**
Total fatty acids	**97.7**
Unidentified compounds	**2.3**
Sum of omega-6 fatty acids	38.5
Sum of omega-3 fatty acids	1.3
Omega-6:Omega-3 ratio	29.13

Note: Analyzed by gas chromatography with flame ionization detection.

The composition of the lipid mixture was further characterized using a representative batch of oat oil PL40, as analyzed by normal-phase high-performance liquid chromatography (HPLC). The sample contained a total polar lipid content of 43.9%, and phospholipid and glycolipid contents of 24.0% and 19.9%, respectively. The phospholipid profile, expressed both as a percentage of the total polar lipids and as a percentage of the oat oil PL40, is summarized and presented in Table 2.1-2.

Table 2.1-2 Phospholipid Profile of Oat Oil PL40

Phospholipid	Representative Batch Results (40FO-090915)	
	Concentration as % of Total Polar Lipids	Concentration as % of Oat Oil PL40
PC	32.2	14.14
PE	2.9	1.27
PA	2.6	1.14
PG	21.0	9.22
PI	0	0
PS	0	0
Lyso-PC	0	0
Lyso-PE	0	0
Lyso-PA	0	0

Table 2.1-2 Phospholipid Profile of Oat Oil PL40

Phospholipid	Representative Batch Results (40FO-090915)	
	Concentration as % of Total Polar Lipids	Concentration as % of Oat Oil PL40
Lyso-PG	18.0	7.90
Lyso-PI	0	0
Lyso-PS	0	0
n-acyl-PE	15.7	6.89
Acyl-PG	5.1	2.24
Di-acyl-PG	2.6	1.14
Total Phospholipids (as % of total oil)	**100%**	**43.9**

PA = phosphatic acid; PC = phosphatidylcholine; PE = phosphatidylethanolamine; PG = phosphatidylglycerol; PI = phosphatidylinositol; PS = phosphatidylserine.
Note: Analyzed by gas chromatography with flame ionization detection.

The unique glycolipids found in oats are difficult to measure; however, the United States Department of Agriculture (USDA) has published a report detailing the polar lipid profiles of various oat kernels and includes the measurement of glycolipids (Doehlert *et al.*, 2010). Samples of extracts from 18 varieties of oat were analyzed using HPLC with evaporative light scattering detection to quantify the amounts of 6 classes of glycolipids common in oat kernels. The mean values obtained for each glycolipid class are presented in Table 2.1-3. Digalactosyldiacylglycerol and its estolides represent the main glycolipid in oats and comprise 77.4% of the total glycolipids. Considering that the manufacturing process for oat oil PL40 (see Section 2.2) will not modify the polar lipid profile but will only change the ratio of polar lipids to neutral lipids, the data presented by the USDA provides a representative summary of the glycolipid content in Swedish Oat Fiber's product.

Table 2.1-3 Glycolipid Profile of Oat Extract (Comparable to Oat Oil PL40)

Glycolipid	Mean concentration in Kernel Flour Extracts of 18 Varieties of Oat Determined by HPLC-ELSD (Doehlert *et al.*, 2010) (mg of lipid/100 g flour)	Percentage of Total Glycolipids
ASG	59.4	7.4%
GC	8	1.0%
Diacyl-DGDG	38.3	4.8%
Acyl-DGDG	161	20.2%
DGDG	418	52.4%
DGMG	13.9	1.7%
Diacyl-TriGDG	13.1	1.6%
Acyl-TriGDG	16.0	2.0%
TriGDG	59.0	2.0%
TriGMG	2.5	0.3%
Acyl-tetraGDG	6.5	0.8%
TetraGDG	2.4	0.3%
Total	**798.1**	**100%**

ASG = acyl steryl glucoside; GC = glucocerebroside; DGDG = digalactosyldiacylglycerol; DGMG = digalactosylmonoglycerol; ELSD = evaporative light scattering detection; GDG = galactosyldiacylglycerol; GMG = galactosylmonoacylglycerol; HPLC = high-performance liquid chromatography.

2.2 Manufacturing

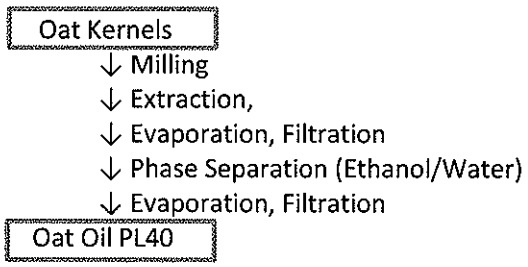
The manufacturing process to produce oat oil PL40 is conducted in accordance with the principles of current Good Manufacturing Practices (cGMP), the principles of Hazard Analysis and Critical Control Points (HACCP), and the Food Safety System Certification (FSSC 22000) standard using food-grade ingredients and equipment commonly used in food manufacture.

The production process can be divided into several stages: reception and preparation of the oats; partial extraction; clarification by centrifugation; evaporation; fractionation; and final evaporation. A schematic of the overall manufacturing process is provided in Figure 2.2-1.

Within its FSSC 22000 program, Swedish Oat Fiber has a purchasing policy in place, including material specifications. Suppliers are only authorized after auditions confirming appliance to European Union (EU) food standards for oats. The most commonly used (but not sole) oat variety used by Swedish Oat Fiber is Belinda, a Swedish spring variety of oats. Swedish Oat Fiber may, in the future, produce oat oil PL40 in the U.S. using locally sourced oats and would utilize a similar vetting process to ensure that the source material is of an acceptable quality for use in food. Manufacture occurs in Sweden using oats sourced from either Sweden or Finland. Prior to the transport of kernels to the processing facility, they are first heat-treated to reduce the moisture content to 11 to 12% to inactivate endogenous lipases and thereby reduced the development of rancidity during transport. Upon arrival at the production facility, the oats are first checked for quality then milled and sieved. The sieving segregates the kernels into a coarse and fine fraction, and the course, fiber-rich, bran fraction is checked for β-glucan content, moisture, and particle size. Partial fat extraction utilizing ethanol is conducted to obtain oat oil extract. The extract is then clarified by centrifugation and evaporation.

Using water and ethanol, the oat oil extract is then fractionated to remove nonpolar lipids and concentrate the polar lipid fraction, which takes place by gravity at room temperature (20°C) in a closed system with minimal oxygen impact. The fractionated oat extract (approximately 60% dry matter) is filtered using cartridge polypropylene filters and then clarified/concentrated with a final evaporation step, resulting in oat oil PL40 containing a standardized polar lipid content of 40%. These gentle chemical and physical processes allow for the oats to be processed without undergoing hydrolysis.

Figure 2.2-1 Schematic Overview of the Manufacturing Process for Oat Oil PL40



The raw materials used in the manufacture of oat oil PL40 are suitable food-grade materials and are used in accordance with applicable U.S. federal regulations.

The final product is imported into the U.S. from Sweden; however, future production of oat oil PL40 may occur in the U.S. using food-grade oats sourced from the U.S. In this situation, the production process of oat oil PL40 will be similar to that used in the facility in Sweden and the facility will follow appropriate

protocols, such as the use of a HACCP plan and compliance with good manufacturing practices, to ensure the oat oil PL40 is safe for use in food and identical to the substance characterized in this GRAS notice.

2.3 Product Specifications and Batch Analyses

2.3.1 Specifications

The proposed chemical specifications for oat oil PL40 are provided in Table 2.3.1-1.

Table 2.3.1-1 Chemical Specifications for Oat Oil PL40

Specification Parameter	Specification	Method
Assay	≥ 30% of substances insoluble in acetone	AOCS Ja 4-46
Description	Oil with a yellowish-brown color	Visual
Identification		
Polar lipids (%w/w)	> 35	Internal method LS-W-01
Purity		
Loss on drying	< 2%	Internal method LS-W-03
Acid value	< 30 mg KOH/g	Mettler Toledo application, M621-2012
Peroxide value	< 10 meq O_2/kg fat	Mettler Toledo application M624-2012
Arsenic	< 0.1 mg/kg	MNKL No 161 1998 mod
Lead	< 0.05 mg/kg	MNKL No 161 1998 mod
Mercury	< 0.01 mg/kg	EN 16277:2012

Microbiological specifications and specifications for other potential impurities are provided in Table 2.3.1-2. Impurities from oat farming, harvesting, and storage (*i.e.*, pesticides and mycotoxins) are effectively controlled by the farms and associated facilities as part of the task of producing "food-grade" oats. Furthermore, concentration of deoxynivalenol in oat oil PL40 is unlikely to occur due to this mycotoxin being water soluble and unlikely to dissociate into the lipid fraction during manufacture.

Table 2.3.1-2 Microbiological Specifications and Specifications for Other Potential Impurities for Oat Oil PL40

Specification Parameter	Specification	Method
Microbiological		
Aerobic plate count (CFU/g)	≤ 1,000	3M 01/01-09/89
Yeast (CFU/g)	≤ 100	NMKL 144
Molds (CFU/g)	≤ 100	NMKL98,2005
Enterobacteriaceae (CFU/g)	≤ 10	NMKL Method 144
Aerobic spores (CFU/g)	≤ 1	Internal method Eurofins
Other		
Cadmium (ppm)	< 0.05	NMKL No 161 1998 mod
Residual ethanol (ppm)	< 500	GC-FID
Pesticide residues	According to 40 CFR §180[a] (U.S. EPA, 2018)	SLVM917, SLVK1f4m016.1, Eurofins
Deoxynivalenol (µg/kg)	< 40	Eurofins internal method

CFR = Code of Federal Regulations; CFU = colony-forming units; EU = European Union; GC-FID = gas chromatography with flame ionization detector; ppm = parts per million.

[a] 40 CFR §180 – Tolerances and Exemptions for Pesticide Chemical Residues in Food.

2.3.2 Batch Analysis

The results of 4 non-consecutive lots of oat oil PL40 shows that the ingredient is manufactured consistent with the proposed chemical specifications and microbiological product specifications (Tables 2.3.2-1 and 2.3.2-2). Complete certificates of analysis for these4 lots are provided in Appendix B.

Table 2.3.2-1 Summary of the Chemical Product Analysis for 4 Lots of Oat Oil PL40

Parameter	Specification	Manufacturing Lot			
		PL40-2017-0102	PL40-20170106	40FO-071216	40FO-131216
Description	Oil with a yellowish brown color	Complies	Complies	Complies	Complies
Identification					
Polar lipids (%w/w)	> 35	44.0	41.9	44.7	42.4
Purity [a]					
Loss on drying (%)	< 2	0.333	0.307	0.730	0.235
Acid value (mg KOH/g)	< 30	NA	NA	9.8	NA
Peroxide value (meq O_2/kg fat)	< 10	1.78	1.10	0.53	2.45
Lead (mg/kg)	< 0.05	< 0.04	<0.04	<0.04	<0.04

NA = not assessed.

[a] Arsenic and mercury are not typically contamination concerns in Nordic oats in general and are monitored by the oat supplier. Routine analysis of production lots is therefore not necessary. As part of their control plan, Swedish Oat Fiber performs yearly tests for arsenic and mercury.

Table 2.3.2-2 Summary of Impurity Analysis for 4 Representative Lots of Oat Oil PL40

Specification Parameter	Specification	Manufacturing Lot			
		PL40-2017-0102	PL40-20170106	40FO-071216	40FO-131216
Microbiological					
Aerobic plate count (CFU/g)	≤ 1,000	< 3	< 3	< 3	< 3
Yeast (CFU/g)	≤ 100	< 2	< 2	< 2	< 2
Molds (CFU/g)	≤ 100	< 2	< 2	< 2	< 2
Enterobacteriaceae (CFU/g)	≤ 10	< 1	< 1	< 1	< 1
Aerobic spores (CFU/g)	≤ 1	< 1	< 1	< 1	< 1
Other					
Cadmium (ppm)	< 0.05	< 0.02	< 0.02	<0.02	< 0.02
Residual ethanol (ppm)	< 500	59.0	79.4	79.1	54.9
Pesticide residues	According to 40 CFR §180[b] (U.S. EPA, 2018)	< LOD	< LOD	< LOD	< LOD

CFR = Code of Federal Regulations; CFU = colony-forming units; LOD = limit of detection; NA = not available for the batch; ppm = parts per million.

[a] Exact values were not reported for several parameters in this lot of oat oil PL40 but were reported to comply with the specified limit.

[b] 40 CFR §180 – Tolerances and Exemptions for Pesticide Chemical Residues in Food.

Additionally, 4 production lots of oat oil PL40 were analyzed for deoxynivalenol and were all found to contain less than the limit of detection (*i.e.*, 20 µg/kg) (certificates of analysis have been provided in Appendix B).

2.4 Stability

The stability of oat oil PL40 under normal conditions of storage (*i.e.*, at room temperature and at 4°C, stored in the dark in plastic 500-mL containers) was evaluated in a series of tests by Swedish Oat Fiber. Among the samples examined, water content slightly exceeded the specified value in 1 production lot after 9 months and remained within the specification limit in the other 3 production lots for 24 months. Peroxide values in the oat oil PL40 production lots were within the specified limit for 12 months. Thus, the available data on oxidation of oat oil PL40 (*i.e.*, peroxidation value) support the stability of oat oil PL40 under appropriate conditions for up to 12 months. The results from the stability studies have been provided in Appendix B.

Part 3. §170.235 Dietary Exposure

3.1 Estimated Intake of Oat Oil PL40

3.1.1 Methods

An assessment of the anticipated intake of oat oil PL40 as an ingredient under the intended conditions of use (see Table 1.3-1) was conducted using data available in the 2015-2016 cycle of the U.S. National Center for Health Statistics (NCHS)'s National Health and Nutrition Examination Survey (NHANES) (CDC, 2018a,b; USDA, 2018). A summary of the survey and methodology employed in the intake assessment of oat oil PL40 along with the pertinent results is presented herein.

The NHANES data are collected and released in 2-year cycles with the most recent cycle containing data collected in 2015-2016. Information on food consumption was collected from individuals *via* 24-hour dietary recalls administered on 2 non-consecutive days (Day 1 and Day 2). Sample weights were incorporated with NHANES data to compensate for the potential under-representation of intakes from specific populations and allow the data to be considered nationally representative (CDC, 2018a,b; USDA, 2018). The NHANES data were employed to assess the mean and 90th percentile intake of oat oil PL40 for each of the following population groups:

- Infants and young children, up to and including 2 years;
- Children, ages 3 to 11;
- Female teenagers, ages 12 to 19;
- Male teenagers, ages 12 to 19;
- Female adults, ages 20 and up;
- Male adults, ages 20 and up; and
- Total population (all age and gender groups combined).

Estimated intake data of oat oil PL40 by the U.S. population were generated through computer collation of consumption data originating from individual dietary records, which detailed food items ingested by each survey participant[1]. Daily intake estimates of oat oil PL40 represent projected 2-day averages for each

[1] Statistical analysis and data management were conducted in DaDiet Software (Dazult Ltd., 2018). DaDiet Software is a web-based software tool that allows accurate estimate of exposure to nutrients and to substances added to foods, including contaminants,

individual from Day 1 and Day 2 of NHANES 2015-2016; these average amounts comprised the distribution from which mean and percentile intake estimates were determined. Mean and percentile estimates were generated incorporating survey weights in order to provide representative intakes for the entire U.S. population. *"Per capita"* intake refers to the estimated intake of oat oil PL40 averaged over all individuals surveyed, regardless of whether they consumed food products in which oat oil PL40 is proposed for use, and therefore includes individuals with "zero" intakes (*i.e.*, those who reported no intake of food products containing oat oil PL40 during the 2 survey days). "Consumer-only" intake refers to the estimated intake of oat oil PL40 by those individuals who reported consuming food products in which the use of oat oil PL40 is currently under consideration. Individuals were considered "consumers" if they reported consumption of 1 or more food products in which oat oil PL40 is proposed for use on either Day 1 or Day 2 of the survey.

The estimates for the intake of oat oil PL40 was generated using the maximum use level indicated for each intended food use, as presented in Table 1.3-1, together with food consumption data available from the 2015-2016 NHANES datasets. The results for these assessments are presented in Section 3.1.2.

3.1.2 Intake Estimates for Oat Oil PL40

Swedish Oat Fiber has generated estimates for the intake of oat oil PL40 using the maximum use level indicated for each intended food use, as presented in Table 1.3-1, together with food consumption data available from the 2015-2016 cycle of the U.S. NCHS's NHANES. The summary of these data for daily intake of oat oil PL40 and daily per kilogram body weight intake of oat oil PL40 can be found in Tables 3.1.2-1 and 3.1.2-2, respectively. Although younger populations were identified as the groups having greater exposures to oat oil PL40 on a body weight basis, relative to other groups, the products containing oat oil PL40 will not serve as their primary source of fat or nutrients in the diet (*e.g.*, baby foods complement milk or infant formula and do not replace it entirely). Estimates described herein assume *all* products, including those consumed by younger individuals, would contain oat oil PL40 at the maximum intended use levels. In actuality, these products would, in the worst case, only be consumed incidentally, and intakes described in the older populations (*i.e.*, not more than 59 and 143 mg/kg body weight/day at the mean and 90th percentile, respectively, for male teenagers) are expected to be more accurate estimates of dietary exposure among the intended population. It is unlikely that oat oil PL40 will have 100% market penetration in all identified food categories.

Table 3.1.2-1 Summary of the Estimated Daily Intake of Oat Oil PL40 from Proposed Food Uses in the U.S. by Population Group (2015-2016 NHANES Data)

Population Group	Age Group (Years)	*Per Capita* Intake (g/day)		Consumer-Only Intake (g/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Infants and Young Children	0 to 2	2.5	6.5	82.5	545	3.1	7.1
Children	3 to 11	3.3	7.4	96.9	1,142	3.4	7.5
Female Teenagers	12 to 19	2.7	6.6	91.1	438	3.0	7.0
Male Teenagers	12 to 19	3.3	8.0	89.2	427	3.7	8.5
Female Adults	20 and up	3.2	7.4	94.8	2,083	3.4	7.5
Male Adults	20 and up	3.6	9.4	90.8	1,775	4.0	9.6
Total Population	All ages	3.3	8.0	92.6	6,410	3.6	8.2

n = sample size; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

food additives and novel ingredients. The main input components are concentration (use level) data and food consumption data. Data sets are combined in the software to provide accurate and efficient exposure assessments.

Table 3.1.2-2 Summary of the Estimated Daily Per Kilogram Body Weight Intake of Oat Oil PL40 from Proposed Food Uses in the U.S. by Population Group (2015-2016 NHANES Data)

Population Group	Age Group (Years)	Per Capita Intake (mg/kg bw/day)		Consumer-Only Intake (mg/kg bw/day)			
		Mean	90th Percentile	%	n	Mean	90th Percentile
Infants and Young Children	0 to 2	236	657	82.4	540	286	738
Children	3 to 11	129	285	97.0	1,138	133	291
Female Teenagers	12 to 19	47	109	91.0	430	52	112
Male Teenagers	12 to 19	52	128	89.2	426	59	143
Female Adults	20 and up	44	105	94.8	2,072	47	106
Male Adults	20 and up	41	103	90.7	1,751	45	111
Total Population	All Ages	61	140	92.6	6,357	66	146

bw = body weight; n = sample size; NHANES = National Health and Nutrition Examination Survey; U.S. = United States.

3.1.3 Intake Estimates for Major Constituents of Oat Oil PL40

Oat oil PL40 is comprised of 24.0% phospholipids, 19.9% glycolipids, and 56.1% triglycerides (see Section 2.1). These individual constituents of oat oil PL40 are naturally occurring in both oats and other vegetables and vegetable oils. As part of the assessment of the safety of oat oil PL40, Swedish Oat Fiber made comparisons between the estimated intake of the constituents in oat oil PL40 to intakes of these substances from certain other foods which have safe histories of use. Estimated intakes for the constituents of oat oil PL40 (triglycerides, phospholipids, and glycolipids) are presented below and a discussion of these intakes compared with those from other commonly consumed foods is provided in Section 6.3.

The mean estimated intake of phospholipids and triglycerides from the intended use of oat oil PL40 among the general population are 0.86 g/day and 2.02 g/day, respectively. Among male adults (the highest consumer group) in the 90th percentile intake group, the estimated intake of phospholipids and triglycerides from the intended uses of oat oil PL40 is 2.3 g/day and 5.39 g/day, respectively.

In order to compare the estimated intake of glycolipids with the available background consumption data, the estimated intake of oat oil PL40 on a per kilogram body weight basis was used. The mean consumer-only intakes of oat oil for the total population and 90th percentile consumer-only intakes of oat oil for the highest and most relevant consumers (male teenagers; see Section 3.1.2 for justification) were 66 mg/kg body weight/day and 143 mg/kg body weight/day, respectively, which corresponds to a glycolipid intake of 13.1 to 28.5 mg/kg body weight/day, respectively.

Part 4. §170.240 Self-Limiting Levels of Use

No known self-limiting levels of use are associated with oat oil PL40.

Part 5. §170.245 Experience Based on Common Use in Food Before 1958

Not applicable.

Part 6. §170.250 Narrative and Safety Information

6.1 Introduction

The safety of Swedish Oat Fiber's oat oil PL40 under the conditions of its intended uses are based on scientific procedures. In particular, the safety of the consumption of oat oil PL40 as an ingredient in food and beverages is substantiated by the natural occurrence of this oil in oats, which are commonly consumed by humans as part of a normal diet as well as by the history of safe consumption of the constituents in oat oil PL40 (triglycerides, phospholipids, and glycolipids) in large population groups for many years without reported adverse effects at levels similar to the proposed use levels.

The safety of oat oil PL40 was further supported through information on its metabolic fate and studies of similar products (Fabuless, also known as Olibra) in animals and humans. A comprehensive literature search was performed to identify studies pertaining to the safety of oats, oat oil, and its major constituents. Oat oil preparations have been investigated in mice and rats to examine its potential protective effects against certain pathological states. These studies, while they are not designed to investigate safety, can provide additional support that the administration of oat oil is not associated with adverse effects and are able to mitigate toxicological effects (*e.g.*, testicular biomarkers of toxicity, obesity, formation of pre-neoplastic hepatic lesions) under specific conditions. The oat oils tested in these studies are not oat oil PL40 and would therefore have different ratios of polar lipids to triglycerides, however, the findings from these large doses are relevant to the safety of oat oil PL40 under the intended conditions of use in food and beverages and support a conclusion that oat oil PL40 is GRAS for the intended conditions of use.

As the levels of historical consumption of oat lipids from oats are greater than the estimated intake of oat oil PL40 based on its proposed uses in food and beverages it may be concluded that consumption of oat oil PL40 is safe. However, since all available information pertinent to the safety of a substance must be evaluated as part of a GRAS conclusion, unpublished toxicological studies (consisting of a 28-day study in Sprague-Dawley rats and a 28-day study in Beagle dogs) and genotoxicity studies (consisting of a bacterial reverse mutation assay and a chromosome aberration test in human blood lymphocytes) of the commercial oat oil PL40 ingredient have been included in the notice. These studies were originally commissioned to fulfill regulatory requirements for the authorization of oat oil PL40 as a pharmaceutical excipient and were not published because this was not a requirement for submission at the time. The findings from these studies corroborate the safety of oat oil PL40 as no adverse effects or genotoxicity was reported.

The following sections summarize the available data on oat oil PL40 which are used to support the above statements.

6.2 History of Safe Consumption

Oat oil PL40 has not been the subject of previous GRAS assessments and has not been previously used in food in the U.S. Nevertheless, a commercial vegetable oil emulsion comprised of oat oil and palm oil in a 6:94 ratio, known as Fabuless or Olibra, is commercially available in the U.S., Sweden, and Finland, and has been used in meal replacement beverages, dairy products, and ultra-high temperature processing milk since 1997 in the U.S., with introduction into Sweden and Finland in 2005.

Oat oil PL40 consists of 2 primary classes of lipids: triglycerides (neutral lipids), and polar lipids, which are further subdivided into phospholipids and glycolipids as discussed in Section 2.1. The compounds within each group are structurally similar to one another and to other substances of the same structural class found in common foods. Triglycerides, phospholipids, and glycolipids share common metabolic fates and have the same safety profiles as other substances found in food which reside within the same structural class (see Section 6.4). Triglycerides and phospholipids are also endogenously synthesized in humans to fulfill particular metabolic functions such as energy storage, cellular membrane transporters and/or receptors, cell-to-cell aggregation and dissociation, and for brain and eye functions (Brandenburg *et al.*, 2010; Gimenez *et al.*, 2011).

Oats also contain epoxy- and hydroxy-fatty acids at concentrations in the total oil of up to 3.3% and 0.4%, respectively (corresponds to approximately 33 and 4 mg/g, respectively]) (Leonova *et al.*, 2008). Hydroxy- and epoxy-fatty acids are produced by an endogenous enzymatic process that commonly uses oleic acid as a substrate, although linoleic and linolenic acids may also be used by the oat plant (Leonova *et al.*, 2008; Doehlert *et al.*, 2010; Meesapyodsuk and Qiu, 2011). Hydroxy-fatty acids are commonly measured in the polar lipid fraction, whereas epoxy-fatty acids are mainly present in the neutral lipid fraction of the total fats (Leonova *et al.*, 2008; Doehlert *et al.*, 2010; Meesapyodsuk and Qiu, 2011). The occurrence of hydroxy- and epoxy-fatty acids have also been described in plant and seed oils in general, including flax seeds, wheat seeds, corn seeds, and soybeans and is produced in these plants *via* similar enzymatic modification of fatty acids (Manson, 1980; Grechkin *et al.*, 1991; Blée and Schuber, 1992). Xia and Budge (2017) noted that epoxy fatty acids can be generated at levels of up to 14.24 mg/g in olive oil and 9.44 mg/g in sunflower oil when used as frying oils. Marmesat *et al.* (2008) reported that hydroxy fatty acids in fried sunflower oil ranged from 1.9 to 5.5 mg/g, which is similar to the amount in oat oil. Under the intended conditions of use of oat oil and considering the relatively greater levels of use of frying oils, it is estimated that the exposure to epoxy- and hydroxy-fatty acids from oat oil PL40 will be similar to or less than the amount from the consumption of frying oils in food even when any potential concentration effect of the manufacturing process.

Swedish Oat Fiber has expressed the estimated consumption of oat oil PL40 in terms of its major constituents (triglycerides, phospholipids, and glycolipids) to discuss its history of safe relative to the consumption of these constituents in the normal diet.

Among other cereal grains, oats contain high levels of lipids, although in relative terms, they do not reach a level comparable to that of oil seed crops, which are conventionally the commercial sources of edible plant-derived oils (reviewed in Zhou *et al.*, 1999). The ratio of triglycerides to polar lipids has been modified in oat oil PL40 during the production process. Therefore, it is prudent to express the estimated intake of oat oil PL40 in terms of triglycerides, phospholipids, and glycolipids. Each class of substances in oat oil PL40 (*i.e.*, triglycerides, phospholipids, and glycolipids) are considered in terms of their occurrence in the diet and their history of safe consumption below.

The fatty acid and polar lipid constituents of oat oil are also naturally occurring within the diet from oats, as well as from other sources that are consumed regularly as part of the normal human diet. For example, Armand (2013) reported individuals consume 50 to 150 g of fatty acids per day. Consumers of a typical western diet consume approximately 2 to 8 g of dietary phospholipids (polar lipids) per day (Cohn *et al.*, 2010). Concentrations of glycolipids in soybeans has been reported to range from 60 to 200 mg/kg dry weight while glycolipids comprise 16% of soy lecithin on a dry weight basis (Leray, 2015). While consumption of soybeans is low in the U.S. population (40 g/person/year), the average per capita consumption of soybeans among the Japanese population has been estimated to be 59.4 g/person/day (Otsuka, 2019). This corresponds to an approximate intake of 3.6 to 11.9 mg glycolipids/day without any

reported detrimental effect. In a recent evaluation by EFSA (2017), the estimated mean intakes for lecithin ranged from 50 to 365 mg/kg body weight/day and the estimated 95th percentile intakes ranged from 109 to 520 mg/kg body weight/day. Based on a glycolipid content of 16% in lecithin, these intakes correspond to intakes of 8 to 58.4 mg glycolipids/kg body weight/day and 17.4 to 83.2 mg glycolipids/kg body weight/day for mean and 95th percentile intakes, respectively, for infants to the elderly (3 months to over 65 years). Glycolipids, such as MGDG and DGDG, are also common in plant cells where they are synthesized and integrated into cellular membranes and photosynthetic organelles and are present in eggs, dairy, and cereals (Andersson *et al.*, 1995; Leray, 2015; ScienceDirect, 2019).

Under the intended conditions of use of oat oil PL40 in foods and beverages, the mean estimated intake of oat oil PL40 for the total population is 3.6 g/day while the greatest estimated exposure to oat oil PL40 is up to 9.6 g/day among male adults (20+ years of age) in the 90th percentile of consumers (see Section 3.1). Oat oil PL40 is comprised of 24.0% phospholipids, 19.9% glycolipids, and 56.1% triglycerides (see Section 2.1). The estimated intake of phospholipids and triglycerides from the intended use of oat oil PL40 among the general population are 0.86 g/day and 2.02 g/day, respectively. Among male adults (the highest consumer group) in the 90th percentile intake group, the estimated intake of phospholipids and triglycerides from the intended uses of oat oil PL40 is 2.3 g/day and 5.39 g/day, respectively. These values are less than the background intakes of triglycerides and phospholipids in the diet.

In order to compare the estimated intake of glycolipids with the available background consumption data, the estimated intake of oat oil PL40 on a per kilogram body weight basis was used. The mean consumer-only intakes of oat oil for the total population and 90th percentile consumer-only intakes of oat oil for the highest and most relevant consumers (male teenagers; see Section 3.1 for justification) were 66 mg/kg body weight/day and 143 mg/kg body weight/day, respectively, which corresponds to a glycolipid intake of 13.1 to 28.5 mg/kg body weight/day, respectively.

Table 6.2-1 provides a summary of the comparison between the background intake of triglycerides, phospholipids, and glycolipids in the diet or specific dietary ingredients to the estimated intake of triglycerides, phospholipids, and glycolipids from the intended uses of oat oil PL40 discussed in Section 1.3.

Table 6.2-1 Comparison Between the Estimated Intakes of the Constituents of Oat Oil PL40 and Background Sources of these Constituents

Constituent	Estimated Intake from Oat Oil PL40[a]		Background Consumption Without Adverse Effects	
Triglycerides	Mean[b]: 90th percentile[c]:	0.86 g/day 5.39 g/day	50 to 150 g/day; estimated from total diet [d]	
Phospholipids	Mean[b]: 90th percentile[c]:	2.02 g/day 2.30 g/day	2 to 8 g/day; estimated from total diet [e]	
Glycolipids	Mean[b]: 90th percentile[f]:	13.1 mg/kg bw/day 28.5 mg/kg bw/day	Mean: 95th percentile	8 to 58.4 mg/kg bw/day[g] 17.4 to 83.2 mg/kg bw/day[g] Estimated from intake of soy lecithin

bw = body weight.

[a] The estimated intakes of the constituents of oat oil PL40 were calculated from the estimated intakes of oat oil PL40 provided in this notice and the composition of oat oil PL40 which is approximately 24.0% phospholipids, 19.9% glycolipids, and 56.1% triglycerides (see Section 2.1).

[b] Total population.

[c] Male adults (20 years and older).

[d] Armand (2013).

[e] Cohn *et al.* (2010).

[f] Male teenagers (12 to 19 years old).

[g] Calculated from the estimated intake of soy lecithin based on a glycolipid content of 16% (Leray, 2015; EFSA, 2017).

Swedish Oat Fiber concluded that, taking the above into account, the constituents of oat oil PL40 are naturally occurring substances, which are commonly found in other foods. The estimated intakes of triglycerides and phospholipids from the intended uses of oat oil PL40 are less than the amounts estimated to be consumed from other dietary sources, while the estimated intake of glycolipids from the proposed uses of oat oil PL40 are within the range estimated from lecithin intake. Swedish Oat Fiber notes that the background intake of glycolipids calculated from lecithin consumption alone is conservative and does not account for intake of glycolipids from all dietary sources, which can be large and difficult to estimate considering its ubiquity in foods. Swedish Oat Fiber therefore concludes that the consumption of oat oil PL40 under the intended conditions of use will result in exposures to triglycerides, phospholipids, and glycolipids that are within the range for these substances that is typical from other dietary sources and are not expected to give rise to safety concerns based on their history of safe consumption.

6.3 Absorption, Distribution, Metabolism, and Excretion

Oat oil is a component of the oat grain seeds and is expected to exhibit similar metabolic fates to that of other edible vegetable oils and fatty acids derived from common sources. The available data on the metabolic fate of the constituents of oat oil support that these substances are metabolized through normal metabolic processes for lipids to innocuous products which are also obtained from other foods in the diet.

According to the Institute of Medicine (IOM, 2005), when ingested, dietary lipids are hydrolyzed by buccal, gastric, pancreatic and intestinal lipases. These lipases catalyze the breakdown of triacylglycerides into a mixture of free fatty acids and acylglycerols. Due to the long-chain fatty acid lipids in oat oil, it is expected that triglycerides from oat oil may persist into the upper portion of the small intestine, where bile salts are able to emulsify lipid droplets and pancreatic lipases may hydrolyze long-chain triacylglycerols before absorption.

Dietary phospholipids are hydrolyzed *via* pancreatic phospholipase A_2 in the gastrointestinal lumen (IOM, 2005). The lyso-phospholipids are then re-esterified and may then be assembled together with cholesterol, free fatty acids, glycerols, and apoproteins into lipoproteins. These lipoproteins and lyso-phospholipids are absorbed through the intestinal mucosal cells through the small intestine and may enter the circulation through the thoracic duct where they are subjected to first-pass metabolism in the liver (IOM, 2005). Most newly absorbed fatty acids are stored as triacylglycerol in adipose tissue but, when required (*i.e.*, during exercise or fasting states), may be hydrolyzed by hormone-sensitive lipases to free fatty acids, which are liberated into the circulation and can be oxidized by skeletal muscles or the liver. The oxidative process for fatty acids produces only carbon dioxide and water, with small amounts of ketone bodies produced by fatty acid oxidation that may be excreted in the urine.

Pancreatic enzymes in the gastric lumen similarly digest glycolipids, which results in free fatty acids and a sugar moiety that are each subsequently absorbed and metabolized *via* well-established pathways as previously noted (Andersson *et al.*, 1995). The biological effect of glycolipids from the diet is equivalent to their composite lipids and sugars. Compositional analysis of glycolipids in oats indicate that the likely hydrolysis products following digestion in the gastric lumen will be galactose, glycerol, fatty acids, phosphate, and plant sterols.

The gastrointestinal metabolic properties of oat oil in yogurt, specifically a vegetable-oil emulsion of oat oil and palm oil (Fabuless), were characterized in healthy humans *via* a validated intestinal perfusion digestion study (Knutson *et al.*, 2010). The study was a randomized, double-blind, placebo-controlled crossover study, wherein subjects (16 individuals) consumed yogurt (control) or yogurt with added Fabuless. Samples were collected from the stomach and prior to the proximal jejunum. Gastric and intestinal samples were

drawn before the infusion of the yogurt products and at regular 30-minute intervals at up to 180 minutes post-infusion.

Hydrolysis of these lipids was demonstrated to start in the stomach, with approximately 76.2% of the lipids in the test product remaining as triacylglycerides and small amounts of diacylglycerides and monoacylglycerides present. Up to 180 minutes post-exposure, triacylglycerides continued to be the major component recovered in the stomach, with approximately 475 mg of the test lipids (out of 8.5 g) being recovered in the stomach. Samples obtained from the proximal part of the jejunum demonstrated that most lipids were almost fully hydrolyzed to free fatty acids, with notably more free fatty acids detected from those administered the test yogurt compared to the control. Enrichment of the long-chain saturated fatty acids (especially palmitic acid) were reported at the jejunum compared to the baseline composition of the yogurts, which was reflected in both the control and test samples. The investigators reported no significant difference in gastric lipase activity and stomach pH when comparing samples obtained after exposure to the control and test yogurts.

The study investigators also reported crystal structures in the proximal jejunum which were determined to consist of palmitic acid and, according to the investigators, "*The crystallization of hydrolyzed ingested lipids in the gastrointestinal lumen makes it possible that sufficient amounts of lipids may reach the ileum and activate a feedback mechanism, such as an ileal brake*", which caused a reduction in digestion and absorption rates and would correlate with the increased satiety reported following ingestion of Fabuless products.

6.4 Toxicological Studies

6.4.1 Subchronic Studies

Oat oil PL40 was evaluated in 28-day oral toxicity studies in Sprague-Dawley rats and Beagle dogs, which complied with the principles of Good Laboratory Practices (Saynor, 2003, 2004 [unpublished and confidential]). These studies were unpublished and are of an insufficient duration to evaluate the safety of oat oil PL40. A summary of the study methods and findings are provided below.

In both 28-day oral toxicity studies, no adverse effects were reported and there were no macroscopic or histopathological test item-related findings. The study authors concluded that the no-observed-adverse-effect levels (NOAEL) was 5,000 mg/kg body weight/day, the highest dose tested, for both studies. Based on the polar lipid content of oat oil PL40, the NOAELs reported in these studies correspond to a NOAEL of 2,000 mg/kg body weight/day for the polar lipid component. These findings corroborate the history of safe use of oat oil PL40 which has been established above.

6.4.1.1 28-Day Repeat Dose Study in Crl:CD(SD) IGS BR Rats

A GLP-compliant 28-day oral toxicity study in Crl:CD(SD) IGS BR rats was conducted in order to determine the toxicity of oat oil PL40 (Saynor, 2003 [unpublished and confidential]). Rats (10/sex/group) were administrated corn oil (control) or oat oil PL40 at doses of 1,250, 2,500, or 5,000 mg/kg body weight/day by gavage (dose volumes were 5 mL/kg body weight for control and high-dose groups, 1.25 mL/kg body weight for the low-dose group and 2.5 mL/kg body weight for the mid-dose group) for 28 days[2]. Animals were observed daily for changes in clinical condition, with ophthalmoscopic examinations performed on control and high-dose animals before the start of dosing and in Week 4. Body weights and food consumption were

[2] A 7-day dose range finding study also was conducted in which rats were administered doses of oat oil ranging from 600 to 5,000 mg/kg body weight/day. Authors reported no adverse effects.

recorded weekly. Blood samples were collected in Week 4 for hematology and clinical biochemistry assessments, with urine samples also collected at the end of the study for analysis of urinary parameters. At the end of the treatment period, animals were subjected to a gross macroscopic necropsy, where selected organs (adrenals, kidneys, spleen, liver, heart, brain, pituitary and thyroids/parathyroids, ovaries, prostate, testes/epididymides) were weighed and subsequently fixed for microscopic examination.

No test article-related deaths were observed during the study; 1 mid-dose female died due to a dosing error (rupture of the esophagus and inflammatory changes in-and-around the thoracic cavity were seen macroscopically). Clinical observations (including some instances of staining in all male groups and for mid- and high-dose females in addition to infrequent occurrences of thinning fur among low-, mid-, and high-dose groups) were considered to be unrelated to the test article; there were also no test item-related ophthalmoscopic findings. No differences in body weight or food consumption were observed between test item-treated groups and controls. No test article-related changes in hematological, clinical chemistry, or urinalysis parameters were observed. Where statistically significant differences were observed, there was either no dose-response relationship (increased hemoglobin distribution width for low-dose males and high-dose females, increased red cell distribution width for high-dose females, increased calcium for low-dose males, increased urea for low- and high dose males, increased cholesterol for low-dose females, increased urine volume and specific gravity for mid-dose males) or the differences were inconsistent between the sexes (increased activated partial thromboplastin time for high dose males only and increased potassium for high-dose females only) and they were therefore considered to be unrelated to administration of the test item.

At necropsy, there were no test item-related macroscopic findings and no differences in organ weights between controls and test item-treated animals. Microscopic findings were generally infrequent, of a minor nature and consistent with the usual pattern of findings in rats of this strain and age. Inflammatory cell foci/myofiber degeneration in the sternum and esophagus of some control and high-dose animals was not associated with any dose-response relationship and was deemed by the study investigators to be associated with dosing procedure (possibly exacerbated by the larger dose volumes used for the control and high-dose groups), rather than any effect of the test item.

6.4.1.2 28-Day Repeat Dose Study in Beagle Dogs

A GLP-compliant 28-day oral toxicity study in dogs was conducted to further investigate the potential toxicity of oat oil PL40 (Saynor, 2004 [unpublished and confidential]). The study was not conducted according to an Organisation for Economic Co-operation and Development test guideline but did meet the requirements of Directive 2001/83/EC (EC, 2001). Beagle dogs (3/sex/group) were administered by gavage corn oil (control) or oat oil PL40 at 1,250, 2,500, or 5,000 mg/kg body weight/day (dose volumes were 5 mL/kg body weight for control and high-dose groups, 1.25 mL/kg body weight for the low-dose group and 2.5 mL/kg body weight for the mid-dose group) for 28 days. Animals were observed twice daily for signs of ill health or overt toxicity. Ophthalmoscopic examinations were performed on control and high-dose animals before the start of dosing and in Week 4. Body weights and food consumption were recorded weekly. Blood samples were collected before the start of the exposure period and in Week 4 for hematology and clinical biochemistry assessments, with urine samples also collected at the end of the study for analysis of urinary parameters. At the end of the treatment period, animals were necropsied and adrenals, kidneys, spleen, liver, heart, brain, pituitary, thyroids/parathyroids, ovaries, prostate, and testes/epididymides) were weighed and fixed for microscopic examination.

There were no deaths, no test item-related clinical signs and no ocular findings related to administration of the test item. No biologically relevant differences in body weight or food consumption were reported between test item-treated group and controls. There were no test item-related differences in hematological, clinical biochemistry or urinalysis parameters between controls and test item-treated groups. At necropsy, there were no differences in organ weights and no macroscopic or microscopic findings related to administration of the test item.

6.4.2 Reproduction and Developmental Considerations

Oat oil PL40 is comprised of triglycerides, phospholipids, and glycolipids which are present in the typical diet in similar or greater amounts than the estimated intake of oat oil PL40 under the intended conditions of use. Reproductive and developmental effects are therefore not expected under the intended conditions of use of oat oil PL40.

6.4.3 Genotoxicity Studies

Genotoxicity is not anticipated following consumption of oat oil PL40 under the intended conditions of use based on the composition of the product and the ubiquity of its constituents in the normal diet, which are readily metabolized to innocuous and endogenous substances *via* normal digestive processes. As such, oat oil PL40 is not genotoxic. Regardless, unpublished *in vitro* genotoxicity studies consisting of a bacterial reverse mutation assay in *Salmonella typhimurium* strains TA98, TA100, TA1535, and TA1537 (Johnson, 2003) and a chromosomal aberration test in cultured human blood lymphocytes (Kumaravel, 2003) were conducted to evaluate the genotoxic potential of oat oil PL40. The *in vitro* chromosomal aberration test is considered a viable alternative to the *in vitro* mammalian cell micronucleus test (which would normally be conducted with the bacterial reverse mutation assay as part of the basic test battery), as it also evaluates clastogenic potential. In both assays, there was no evidence of genotoxicity at up to the highest test concentrations used (5,000 µg/plate and 5,000 µg/mL for the bacterial reverse mutation assay and chromosomal aberration assay, respectively). Due to their unpublished status these genotoxicity studies were only used to corroborate the safety of oat oil PL40 which is supported based on the history of use of the constituents in oat oil PL40.

6.4.4 Other Studies

In a 35-day repeated dose study in male Swiss mice (68/group), animals were administered by gavage 5 mg deltamethrin/kg body weight/day alone or in combination with 6 g/kg body weight/day of a hexane-extracted oat oil, or the oat oil alone without deltamethrin to evaluate the effect of oat oil on reproductive parameters (Ben Halima *et al.*, 2014). There were no statistically significant effects of the oat oil on sperm parameters. Co-administration of the oat oil ameliorated testicular biochemical markers of toxicity and the histopathological changes in the testes caused by deltamethrin exposure.

In a 30-day study, the effect of a supercritical carbon dioxide extract from oat fiber was evaluated in Wistar-Lewis rats (9/group) fed a hypercholesteremic diet supplemented with 70 g/kg diet of the oat extract or soybean oil to evaluate the effect of the extract on diet-induced hypercholesteremia (Tong *et al.*, 2014). There was no statistically significant effect of the oat extract on body weight, body weight gain, food intake, or liver weight relative to the soybean oil control group. Total adipose tissue and white adipose tissue sites were reduced in the oat extract group without any effect on brown adipose tissue, relative to the control group. Liver cholesterol, free cholesterol, cholesterol ester, and liver triglycerides were statistically significantly decreased relative to the control group.

In a study on the modulation of liver preneoplastic lesions, female Sprague-Dawley rats (10/group) were administered diets containing 10% corn oil or 10% oat lipids during a 4-week tumor initiation phase (exposure to diethyl nitrosamine after 70% partial hepatectomy) and a 5-month tumor promotion phase (Li *et al.*, 1999). There were no differences in body weight, liver weights, or growth between the oat lipid and corn oil groups. Oat lipid consumption exerted a protective effect against the formation or pre-neoplastic hepatic foci. I-compounds ("indigenous compounds"), an endogenously produced bulky DNA modification which occurs in response to dietary restriction or consumption of certain unprocessed foods, were increased in the oat lipid group. The study investigators previously (Li *et al.*, 1992) attributed the increase in I-compounds in rats to a sterol present in the oat oil. There is no indication in this study or elsewhere in the literature that suggests these endogenous compounds could form carcinogenic adducts.

6.5 Human Studies

Oat oil is a constituent of Olibra (Fabuless), which is comprised of a final concentration of approximately 6% oat oil. Olibra has been investigated in several published human studies where the highest dose of Olibra was 6 g/day (equivalent to approximately 0.12 g oat oil) and the longest treatment period was 4 months. While the studies were designed to investigate efficacy in promoting satiety and management of body weight, Olibra was well-tolerated (not associated with any adverse effects). The doses reported in these studies are equivalent to the anticipated exposure levels from the use oat oil in food and are supportive evidence that the consumption of oat oil is safe at its intended use levels. The fatty acid profile of Olibra is presented in Table 6.6-1 for the purposes of comparison.

Table 6.6-1 Fatty Acid and Physico-Chemical Features of Oat Oils

Parameter	Oat Oil (Ethanol Extracted)	Conventional Oat Oil (NFS)	Hexane-extracted Oat Oil (Mean of Several Oat Species)	Hexane-Extracted Dal Oats (Range from 3 Cultivars)	Methanol-Extracted Oat Oil	Supercritical Carbon Dioxide Extracted Oat Oil	Hexane-Extracted Oat Oil	Olibra* (Fabuless)
Reference	Swedish Oat Fiber	Bockisch (1998)	Frey and Hammond (1975)	Kalbasi-Ashtari and Hammond (1977)	Li *et al.* (1999)	Tong *et al.* (2014)	Ben Halima *et al.* (2014)	Specification sheet
Fatty Acid Profile								
C14:0 Myristic Acid (%)	0.2	-	-	-	0.2	-	0.25	-
C16:0 Palmitic Acid (%)	16.9	10.5	18.9	15.0 to 16.4	16.0	17.7	17.75	43
C16:1 Palmitoleic (%)	0.2	-	-	-	-	-	0.37	-
C18:0 Stearic Acid (%)	1.7	-	1.7	1.9 to 2.8	2.0	1.5	2.25	4
C18:1 Oleic Acid (%)	37.7	58.5	42.2	39.5 to 43.6	36.9	32.5	41.75	40
C18:2 Linoleic Acid (%)	38.4	-	35.6	36.2 to 39.8	42.5	44.5	35.64	11
C18:3 Linolenic Acid (%)	1.3	-	1.8	2.0 to 2.7	1.5	1.9	1.02	-
C20:0 Arachidic Acid (%)	0.1	-	-	-	-	-	0.19	-
C20:1 Eicosanoic Acid (%)	-	-	-	-	-	-	0.68	-
Vitamin E content (mg/kg)	-	-	-	-	~14.39	726	-	-
Total sterols (mg/100 g)	-			-	~269.4	1,263		-
Solidification point (°C)	-	-15 to -21	-	-	-	-	-	-
Relative density at 40°C	-	0.909	-	-	-	-	-	-
Refractive index (n_D^{40})	-	1.464 to 1.468	-	-	-	-	-	-
Iodine value	-	100 to 115	-	-	-	-	-	-
Unsaponifiable matter (%)	-	1.0 to 2.5	-	-	0.07	-	-	-

- = result not reported; NFS = not further specified.

* Olibra is a commercial vegetable oil emulsion composed of oat oil and palm oil in a 6:94 ratio.

In 3 single-dose crossover studies conducted by Burns *et al.* (2000, 2001, 2002), the effect of Olibra at doses of 5 to 15 g on energy intake and feelings of hunger up to 8 hours post-consumption was evaluated. Subjects did not report any ill effects or discomfort following consumption of Olibra.

In a separate single-dose study, healthy male subjects consumed 8.5 g milk fat (control) or 8.5 g Olibra in yogurt to evaluate the effect of the treatments on orocecal transit time using a marker (Haenni *et al.*, 2009). There were no adverse events reported during the study or the follow-up visit. Orocecal transit time was prolonged in the Olibra group and considered to be due to an ileal brake mechanism that slows gastrointestinal transit time. Knutson *et al.* (2010) investigated the effect of the same dose levels of Olibra on fatty acid concentrations in the proximal jejunum and found that they were increased relative to the milk fat control group, again supporting an ileal brake mechanism.

When male and female subjects were provided a yogurt-based meal replacement drink containing 5 g milk fat and corn oil (control), 12.5 g Olibra (5 g fat added during manufacture), or 12.5 g Olibra (5 g fat added after manufacture) in a single dose study, there were no differences between the groups in terms of adverse physical symptoms, palatability scores, mood ratings, or measures of appetite (Smit *et al.*, 2011). Reduced energy intake was statistically significantly only among subjects in the Olibra group with fat added after manufacture (relative to the control group).

In a 3-week study, 28 subjects were provided 200 g of yogurt with either 5 g milk fat (control) or 5 g Olibra per day (Logan *et al.*, 2006). There were no significant effects of Olibra on body weight or anthropometric measures, and no subjects dropped from the study for test article-related reasons. There was a statistically significant decrease in mean fasting blood glucose in males relative to the control group, although the clinical significance of this finding is unclear according to the study investigator.

There were no effects of an Olibra emulsion (15 g; 4.2 g lipid) on organoleptic properties (pleasantness, visual appeal, smell, taste, palatability) in a test yogurt or muffin when compared to a yogurt or muffin containing a palm olein emulsion (control) in a single-dose palatability study (Chan *et al.*, 2012). Differences were reported when the emulsion was added to water and compared against water alone. Subjects reported increased feeling of fullness when Olibra was provided with yogurt, but not with the muffin or water. There were no significant differences in eating behavior. The study authors indicated that adverse events, if any, were recorded and a discussion on nausea monitoring was outlined. The authors did not provide any findings concerning adverse events, implying by omission that these did not arise in the study.

In a single-dose study, subjects consumed in the first phase yogurt with 35 g milk fat (control) or oat oil lipids and in the second phase, yogurt with 35 g milk fat (control), 14 g oat oil lipids with 21 g milk fat, or 1.8 g oat oil lipids with 33.2 g milk fat (Ohlsson *et al.*, 2014). Subjects reported that 14 g oat lipids were not very palatable and there were reports of discomfort in the gut in the first few hours after exposure. There were statistically significant reductions in plasma postprandial cholecystokinin, glucagon-like peptides 1 and 2, and peptide YY in the 14 g and 35 g oat oil lipid groups. Energy intake was also reduced among women that consumed the yogurt containing 35 g oat oil lipids; however, the effect was not statistically significant. These findings suggest that adverse effects following consumption of large amounts of oat oil, many times greater than the intended use level of oat oil PL40, results in minor, transient gastrointestinal disturbances and changes in postprandial blood biomarkers indicative of a lower glycemic state.

A study among 50 overweight female subjects was performed wherein they first took part in a 6-week weight loss diet program followed by an 18-week weight maintenance program (Diepvens *et al.,* 2007). During the weight maintenance phase, subjects consumed yogurt containing 5 g milk fat (control) or 5 g Olibra (providing 3 g milk fat and 2 g vegetable fat) twice daily. There were no significant differences in tolerance or measured blood parameters between the 2 groups. The subjects in the Olibra group were able to maintain the weight loss, reduced body mass index, and waist circumference from the weight loss phase, whereas subjects in the control group increased those parameters.

Overall, there were no statistically significant adverse effects attributable to consumption of Olibra where the highest dose tested was 6 g/day (equivalent to 0.12 g oat oil/day) at test periods extending up to 4 months. These studies support the safety of oat oil in the diet under the intended conditions of use described in section 1.3.

6.6 Allergenicity

Oat oil PL40 is not anticipated to be a risk of allergenicity or hypersensitivity beyond that of oats themselves. Swedish Oat Fiber has conducted evaluations of oat oil PL40 gluten content demonstrating the absence of gluten from potential contamination of the raw material from gluten grain sources (*e.g.*, wheat, barley, rye) at concentrations below the 20 mg/kg limit for labelling food as gluten-free, and is therefore not expected to present a tolerance issue among persons with celiac disease or gluten intolerance (21 CFR §101.91 – U.S. FDA, 2019).

6.7 GRAS Panel Evaluation

Swedish Oat Fiber has concluded that oat oil PL40 is GRAS for use in conventional food and beverage products, including as an emulsifier in standardized chocolate, as described in Section 1.3, on the basis of scientific procedures. This GRAS conclusion is based on data generally available in the public domain pertaining to the safety of oat oil PL40, as discussed herein, and on consensus among a panel of experts (the GRAS Panel) who are qualified by scientific training and experience to evaluate the safety of food ingredients. The GRAS Panel consisted of the following qualified scientific experts: Joseph Borzelleca, PhD. (Department of Pharmacology and Toxicology, VCU School of Medicine), Robert Nicolosi, PhD. (RJ Nicolosi Inc.), and Gary Williams, MD (Department of Pathology, New York Medical College).

The GRAS Panel, convened by Swedish Oat Fiber, independently and critically evaluated all data and information presented herein, and also concluded that oat oil PL40 is GRAS for use in conventional food and beverage products, including standardized chocolate, as described in Section 1.3, based on scientific procedures. A summary of data and information reviewed by the GRAS Panel, and evaluation of such data as it pertains to the proposed GRAS uses of oat oil PL40 is presented in Appendix A.

6.8 Conclusion

Based on the above data and information presented herein, Swedish Oat Fiber has concluded that oat oil PL40 is GRAS, on the basis of scientific procedures, for use in food and beverage products as described herein. General recognition of Swedish Oat Fiber's GRAS conclusion is supported by the unanimous consensus rendered by an independent Panel of Experts, qualified by experience and scientific training, to evaluate the use of oat oil PL40 in food, who similarly concluded that the proposed uses of oat oil PL40 are GRAS on the basis of scientific procedures.

Oat oil PL40 therefore may be marketed and sold for its intended purpose in the U.S. without the promulgation of a food additive regulation under Title 21, Section 170.3 of the Code of Federal Regulations.

Part 7. §170.255 List of Supporting Data and Information

Andersson L, Bratt C, Arnoldsson KC, Herslöf B, Olsson NU, Sternby B, et al. (1995). Hydrolysis of galactolipids by human pancreatic lipolytic enzymes and duodenal contents. J Lipid Res 36(6):1392-1400.

Armand M (2013). Stratégies de contrôle de la biodisponibilité des lipides. Dans: Fardet A, Souchon I, Dupont D, editors. *Structure des Aliments et Effets Nutritionnels [Food Structure and Nutritional Effects]*. Paris, France: QUAE, pp. 373–413.

Ben Halima N, Ben Slima A, Moalla I, Fetoui H, Pichon C, Gdoura R, et al. (2014). Protective effects of oat oil on deltamethrin-induced reprotoxicity in male mice. Food Funct 5(9):2070-2077. DOI:10.1039/c4fo00190g.

Blée E, Schuber F (1992). Occurrence of fatty acid epoxide hydrolases in soybean (Glycine max). Purification and characterization of the soluble form. Biochem J 282(3):711-714. DOI:10.1042/bj2820711.

Bockisch M (1998). Chapter 4. Vegetable fats and oils. In: *Fats and Oils Handbook*. Urbana (IL): AOCS Press, pp. 174-344 [See p. 313].

Brandenburg K, Garidel P, Gutsmann T (2010). Physicochemical properties of microbial glycopolymers. In: Holst O, Brennan PJ, von Itzstein M, editors. *Microbial Glycobiology: Structures, Relevance and Applications*. San Diego (CA): Academic Press, pp. 759-779.

Burns AA, Livingstone MB, Welch RW, Dunne A, Robson PJ, Lindmark L et al. (2000). Short-term effects of yoghurt containing a novel fat emulsion on energy and macronutrient intakes in non-obese subjects. Int J Obesity Relat Metab Disord 24(11):1419-1425. DOI:10.1038/sj.ijo.0801430.

Burns AA, Livingstone MB, Welch RW, Dunne A, Reid CA, Rowland IR (2001). The effects of yoghurt containing a novel fat emulsion on energy and macronutrient intakes in non-overweight, overweight and obese subjects. Int J Obesity Relat Metab Disord 25(10):1487-1496. DOI:10.1038/sj.ijo.0801720.

Burns AA, Livingstone MB, Welch RW, Dunne A, Rowland IR (2002). Dose-response effects of a novel fat emulsion (Olibra™) on energy and macronutrient intakes up to 36 h post-consumption. Eur J Clin Nutr 56(4):368-377. DOI:10.1038/sj.ejcn.1601326.

CDC (2018a). *National Health and Nutrition Examination Survey (NHANES): 2015-2016*. Hyattsville (MD): Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS). Available at: https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx?BeginYear=2015 [NHANES Home Page last reviewed: October 30, 2018].

CDC (2018b). *National Health and Nutrition Examination Survey (NHANES): 2015-2016 – Dietary Data*. Hyattsville (MD): Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS). Available at: https://wwwn.cdc.gov/nchs/nhanes/search/datapage.aspx?Component=Dietary&CycleBeginYear=2015 [Last updated: July 2018].

Chan Y-K, Strik CM, Budgett SC, Mcgill A-T, Proctor J, Poppitt SD (2012). The emulsified lipid Fabuless (Olibra) does not decrease food intake but suppresses appetite when consumed with yoghurt but not alone or with solid foods: a food effect study. Physiol Behav 105(3):742-748. DOI:10.1016/j.physbeh.2011.08.042.

Cohn JS, Kamili A, Wat E, Chung RW, Tandy S (2010). Dietary phospholipids and intestinal cholesterol absorption. Nutrients 2(2):116-127. DOI:10.3390/nu2020116.

Dazult Ltd. (2018). *DaDiet - The Dietary Intake Evaluation Tool [Software]*. (Version 17.04). Straffan, Ireland: Dazult Ltd. Available online: http://dadiet.daanalysis.com [Last accessed: Aug. 8, 2018].

Diepvens K, Soenen S, Steijns J, Arnold M, Westerterp-Plantenga M (2007). Long-term effects of consumption of a novel fat emulsion in relation to body-weight management. Int J Obes (Lond) 31(6):942-949. DOI:10.1038/sj.ijo.0803532.

Doehlert DC, Moreau RA, Welti R, Roth MR, McMjullen MS (2010). Polar lipids from oat kernels. Cereal Chem 87(5):467-474. DOI:10.1094/CCHEM-04-10-0060.

EC (2001). Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Off J Eur Communities 44(L311):67-128. Available at: http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32001L0083&qid=1445441868949 [Consolidated version: 16/11/2012].

EFSA (2017). Scientific opinion on the re-evaluation of lecithins (E 322) as a food additive. (EFSA Panel on Food Additives and Nutrient Sources added to Food/ANS) (Question no EFSA-Q-2011-00500, adopted: 1 March 2017 by European Food Safety Authority). EFSA J 15(4):4742 [74pp]. DOI:10.2903/j.efsa.2017.4742. Available at: https://www.efsa.europa.eu/en/efsajournal/pub/4742.

Frey KJ, Hammond EG (1975). Genetics, characteristics, and utilization of oil in caryopses of oat species. J Am Oil Chem Soc 52(9):358-362. DOI:10.1007/BF02639196.

Gimenez MS, Oliveros LB, Gomez NN (2011). Nutritional deficiencies and phospholipid metabolism. Int J Mol Sci 12(4):2408-2433. DOI:10.3390/ijms12042408.

Grechkin AN, Kuramshin RA, Latypov SK, Safonova YY, Gafarova TE, Ilyasov AV (1991). Hydroperoxides of alpha-ketols. Novel products of the plant lipoxygenase pathway. Eur J Biochem 199(2):451-457. DOI:10.1111/j.1432-1033.1991.tb16143.x.

Gunstone FD (2005). Vegetable oils. 6. Specialty and minor oils [Oats]. In: Shahidi F, editor. *Bailey's Industrial Oil and Fat Products: Volume 1: Edible Oil and Fat Products: Chemistry, Properties, and Health Effects, 6th Edition*. Hoboken (NJ): John Wiley & Sons, Inc., pp. 213-267 [See p. 240].

Haenni A, Sundberg B, Yazdanpandah N, Viberg A, Olsson J (2009). Effect of fat emulsion (Fabuless) on orocecal transit time in healthy men. Scand J Gastroenterol 44(10):1186-1190. DOI:10.1080/00365520903131999.

IOM (2005). Dietary fats: total fat and fatty acids. In: *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids (Macronutrients)*. (National Academy of Sciences/NAS, Institute of Medicine/IOM, Food and Nutrition Board/FNB, Panel on Micronutrients, Panel on the Definition of Dietary Fiber, Subcommittee on Upper Reference Levels of Nutrients, Subcommittee on Interpretation and Uses of Dietary Reference Intakes, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes). Washington (DC): National Academy Press (NAP), pp. 422-541. Available at: http://www.nap.edu/openbook.php?record_id=10490&page=422.

Johnson M (2003) [unpublished]. *Study Title: Oat Lecithin, FOO: Reverse Mutation in Five Histidine-Requiring Strains of Salmonella typhimurium. [Confidential]*. (Covance Study Number: 2213/7; Covance Report Number: 2213/7-D6171; Dated: September 2003). North Yorkshire, UK: Covance Laboratories Ltd.

Kalbasi-Ashtari A, Hammond EG (1977). Oat oil: refining and stability. J Am Oil Chem Soc 54(8):305-307. DOI:10.1007/BF02672430.

Knutson L, Koenders DJ, Fridblom H, Viberg A, Sein A, Lennernäs H (2010). Gastrointestinal metabolism of a vegetable-oil emulsion in healthy subjects. Am J Clin Nutr 92(3):515-524. DOI:10.3945/ajcn.2009.28941.

Kumaravel TS (2003) [unpublished]. *Study Title: Oat Lecithin, FOO: Induction of Chromosome Aberrations in Cultured Human Peripheral Blood Lymphocytes [Confidential]*. (Covance Study Number: 2213/8; Covance Report Number: 2213/8-D6172; Dated: December 2003). North Yorkshire, UK: Covance Laboratories Ltd.

Leonova S, Shelenga T, Hamberg M, Konarev AV, Loskutov I, Carlsson AS (2008). Analysis of oil composition in cultivars and wild species of oat (*Avena* sp.). J Agric Food Chem 56(17):7983-7991. DOI:10.1021/jf800761c.

Leray C (2015). Lipids and human nutrition. 3.2.6. Glycolipids. In: *Lipids: Nutrition and Health*. Boca Raton (FL): CRC Press, Taylor & Francis Group, pp. 153-155.

Li D, Chen S, Randerath K (1992). Natural dietary ingredients (oats and alfalfa) induce covalent DNA modifications (I-compounds) in rat liver and kidney. Nutr Cancer 17(3):205-216. DOI:10.1080/01635589209514189.

Li D, Wang M, Paul GP, Pitot HC, Dragan Y (1999). Dietary oat lipids-induced novel DNA modifications and suppression of altered hepatic foci formation. Nutr Cancer 33(1):40-45. DOI:10.1080/01635589909514746.

Logan CM, McCaffrey TA, Wallace JM, Robson PJ, Welch RW, Dunne A, et al. (2006). Investigation of the medium-term effects of Olibratrade mark fat emulsion on food intake in non-obese subjects. Eur J Clin Nutr 60(9):1081-1091. DOI:10.1038/sj.ejcn.1602422.

Manson MM (1980). Epoxides is there a human health problem? Br J Ind Med 37(4):317-336. DOI:10.1136/oem.37.4.317.

Marmesat S, Velasco J, Dobarganes M (2008). Quantitative determination of epoxy acids, keto acids and hydroxy acids formed in fats and oils at frying temperatures. J Chromatogr A 1211:129-134.

Meesapyodsuk D, Qiu X (2011). A peroxygenase pathway involved in the biosynthesis of epoxy fatty acids in oat. Plant Physiol 157(1):454-463. DOI:10.1104/pp.111.178822.

Ohlsson L, Rosenquist A, Rehfeld JF, Härröd M (2014). Postprandial effects on plasma lipids and satiety hormones from intake of liposomes made from fractionated oat oil: two randomized crossover studies. Food Nutr Res 58 [11pp.]. DOI:10.3402/fnr.v58.24465.

Otsuka (2019). *Soylution: Soybean Consumption*. Tokyo, Japan: Otsuka Pharmaceutical Co., Ltd. Available at: https://www.otsuka.co.jp/en/nutraceutical/about/soylution/encyclopedia/consumption.html [Last accessed: July 15, 2019].

Saynor S (2003) [unpublished]. *Study Title: Oat Lecithin (FOO): 28 Day Oral (Gavage) Administration Toxicity Study in the Rat [Confidential]*. (Covance Study Number: 2213/005; Dated: November 2003). North Yorkshire, UK: Covance Laboratories Ltd.

Saynor S (2004) [unpublished]. *Study Title: Oat Lecithin (FOO): 28 Day (Gavage) Administration Toxicity Study in the Dog [Confidential]*. (Covance Study No: 2213/006; Dated: March 2004). North Yorkshire, UK: Covance Laboratories Ltd.

ScienceDirect (2019). *Galactosyldiacylglycerol*. Amsterdam, The Netherlands: Science Direct, Elsevier. Available at: https://www.sciencedirect.com/topics/medicine-and-dentistry/galactosyldiacylglycerol [Copyright © 2019 Elsevier B.V.].

Smit HJ, Keenan E, Kovacs EMR, Wiseman SA, Peters HPF, Mela DJ, et al. (2011). No efficacy of processed Fabuless (Olibra) in suppressing appetite or food intake. Eur J Clin Nutr 65(1):81-86. DOI:10.1038/ejcn.2010.187.

Tong L-T, Zhong K, Liu L, Guo L, Cao L, Zhou S (2014). Oat oil lowers the plasma and liver cholesterol concentrations by promoting the excretion of faecal lipids in hypercholesterolemic rats. Food Chem 142:129-134. DOI:10.1016/j.foodchem.2013.07.028.

U.S. EPA (2018). Part 180—Tolerances and exemptions for pesticide residues in foods. In: *U.S. Code of Federal Regulations (CFR). Title 40: Protection of Environment*. (U.S. Enviromental Protection Agency). Washington (DC): U.S. Government Printing Office (GPO). Available at: https://www.govinfo.gov/app/collection/cfr.

U.S. FDA (2019). *U.S. Code of Federal Regulations (CFR). Title 21—Food and Drugs*. (Food and Drug Administration). Washington (DC): U.S. Government Printing Office (GPO). Available at: https://www.govinfo.gov/app/collection/cfr/.

Table of CFR Sections Referenced (Title 21—Food and Drugs)

Part	Section §	Section Title
101—Food labeling	101.91	Gluten-free labeling of food
163—Cacao products	[Full Part]	
170—Food additives	170.3	Definitions
	170.30	Eligibility for classification as generally recognized as safe (GRAS)

USDA (2018). *What We Eat in America: National Health and Nutrition Examination Survey (NHANES): 2015-2016.* Riverdale (MD): U.S. Department of Agriculture (USDA). Available at: http://www.ars.usda.gov/Services/docs.htm?docid=13793#release [Last Modified: July 31, 2018].

Xia W, Budge SM (2017). Techniques for the analysis of minor lipid oxidation products derived from triacylglycerols: epoxides, alcohols, and ketones. Compr Rev Food Sci Food Safety 16(4):735-758. DOI:10.1111/1541-4337.12276.

Zhou M, Robards K, Glennie-Holmes M, Helliwell S (1999). Oat lipids. J Am Oil Chem Soc 67(2):159-169. DOI:10.1007/s11746-999-0213-1.

APPENDIX A
GRAS Panel Consensus Statement Oat Oil PL40

GRAS Panel Consensus Statement Concerning the Generally Recognized as Safe (GRAS) Status of Oat Oil PL40 for Use in Foods

15 August 2019

INTRODUCTION

At the request of Swedish Oat Fiber, a panel of independent scientists (the "GRAS Panel"), qualified by their relevant national and international experience and scientific training to evaluate the safety of food ingredients, was specially convened on 15 August 2019 to conduct a critical and comprehensive evaluation of the available pertinent data and information and to determine whether, under the conditions of intended use as an ingredient in traditional foods, oat oil PL40 would be "Generally Recognized as Safe" (GRAS), based on scientific procedures. The GRAS Panel consisted of the below-signed qualified scientific experts: Joseph Borzelleca, PhD. (Department of Pharmacology and Toxicology, VCU School of Medicine), Robert Nicolosi, PhD. (RJ Nicolosi Inc.), and Gary Williams, MD (Department of Pathology, New York Medical College).

The GRAS Panel, independently and collectively, critically examined a comprehensive package of publicly available scientific information and data compiled from the literature and other published sources based on searches of the published scientific literature conducted through July 2019. In addition, the GRAS Panel evaluated other information deemed appropriate or necessary, including data and information provided by Swedish Oat Fiber. The data evaluated by the GRAS Panel included information pertaining to the method of manufacture and product specifications, analytical data, intended use levels in specified food products, consumption estimates for all intended uses, and comprehensive literature on the safety of oat oil PL40 and its individual constituents.

Following an independent, critical evaluation of such data and information, the GRAS Panel unanimously concluded that under the conditions of intended use in traditional foods described herein, oat oil PL40, meeting appropriate food-grade specifications and manufactured and used in accordance with current Good Manufacturing Practices (cGMP), is GRAS based on scientific procedures. A summary of the basis for the GRAS Panel's conclusion, excluding confidential data and information, is provided below.

COMPOSITION, MANUFACTURING, AND SPECIFICATIONS

The ingredient evaluated by the Expert Panel is oat oil PL40 produced by Swedish Oat Fiber and is marketed under the following synonyms and trade names: SWEOAT© Oil PL40; oat lipid extract; oat polar lipid extract; and vegetable oil (oat). Oat oil PL40 is a yellow-brown oil with a typical oat cereal taste produced from the lipid extraction of oat (*Avena sativa*) kernels. Oat kernels typically contain 8.3% total lipid of which 21% of the oil is polar lipids (glycolipids and phospholipids).

The manufacturing process to produce oat oil PL40 is conducted in accordance with cGMP, the principles of Hazard Analysis and Critical Control Points (HACCP), and the Food Safety System Certification (FSSC 22000) standard using food-grade ingredients and equipment commonly used in food manufacture. Manufacture occurs in Sweden using oats sourced from Sweden or Finland. The oats are first checked for quality then milled and sieved. Partial fat extraction using ethanol is used to obtain oat oil. The oil is then clarified by centrifugation and evaporation. Using water and ethanol, the oat oil is then fractionated to remove nonpolar lipids and concentrate the polar lipid fraction and then clarified/concentrated with a final evaporation step, resulting in oat oil PL40. The resulting lipids are natural constituents of oat oil PL40 and are not modified during the manufacturing process. The final product is imported into the U.S. from Sweden; however, the GRAS Panel recognizes that future production of oat oil PL40 may occur in the U.S. using food-grade oats sourced from the U.S. using the same process in appropriate facilities.

Swedish Oat Fiber has established food-grade specifications for oat oil PL40. The GRAS Panel reviewed analytical data provided for 5 non-consecutive lots of oat oil PL40 and confirmed that the final product complies with the established specifications. The results of spectroscopic data from a representative production lot demonstrate that oat oil PL40 has a polar lipid content of 43.9% and the phospholipid and glycolipid contents were 24.0% and 19.9%, respectively. The remainder (56.1%) was non-polar lipids, which were primarily mono-unsaturated and polyunsaturated fatty acids, as well as some sterols and cholesterol (7.7% to 11.8%, combined, in the total lipids). No wax sterols have been detected in oat oil PL40. The non-polar lipids largely comprise triglycerides, whereas the polar lipid fraction largely comprises glycolipids [digalactosyl diacylglycerol, and monogalactosyl monoacylglyerol (20 to 25%)] and phospholipids [including phosphatidyl choline and N-acyl-phosphatidyl ethanolamine (15 to 20%)]. The unique glycolipids and their concentrations in oats are difficult to measure. The United States Department of Agriculture (USDA) has published a report on the polar lipid profile of methanol extracts from oat kernels which include measures of glycolipids. Considering that the manufacturing process for oat oil PL40 will not modify the polar lipid profile but will only change the ratio of polar lipids to neutral lipids, the GRAS Panel agreed that the data presented by the USDA provides a representative summary of the glycolipid content in oat oil PL40. The GRAS Panel agrees that the results of the batch analyses demonstrate that a consistent product is produced in compliance with the ingredient specifications.

The stability of oat oil PL40 under normal conditions of storage (*i.e.*, at room temperature and at 4°C, stored in the dark in plastic 500 mL containers) was evaluated in a series of tests by Swedish Oat Fiber. Among the samples examined, water content slightly exceeded the specified value in 1 production lot after 9 months and remained within the specification limit in the other 3 production lots for 24 months. Peroxide values in the oat oil PL40 production lots were within the specified limit for 12 months with 3 lots exceeding this limit at 15 months and 1 lot at 35 months, while the remaining lots were within the specified limit for the duration of the storage periods (*i.e.*, 18 and 42 months). Thus, the available data on oxidation of oat oil PL40 (*i.e.*, peroxidation value) support the stability of oat oil PL40 under appropriate conditions for up to 12 months.

INTENDED USE AND ESTIMATED EXPOSURE

Swedish Oat Fiber intends to market oat oil PL40 as a vegetable oil that will fulfill similar roles as other vegetable oils currently on the market in the U.S. Oat oil PL40 may be used as an ingredient in foods as a nutritive source of fats and oils and may either be added to existing products or may replace other vegetable oils within those products. As a nutrient source, the inclusion of oat oil PL40 will be reflected in amendments to the nutrition facts labelling of food, as necessary. It will be used across multiple food and beverage categories as described in Table A-1. Oat oil PL40 is intended to be used as an emulsifier in standardized chocolate due to limitations on the optional additives permitted in chocolate under the relevant standard of identification in the U.S. Code of Federal Regulations (CFR). Swedish Oat Fiber has completed studies which demonstrate the functionality of oat oil PL40 as an emulsifier in chocolate and other foods and beverages.

The GRAS Panel reviewed the estimates for the intake of oat oil PL40 which were generated using the maximum use level indicated for each intended food use, as presented in Table A-1, together with food consumption data available from the 2015-2016 cycle of the U.S. National Center for Health Statistics (NCHS)'s National Health and Nutrition Examination Survey (NHANES). On a consumer-only basis, the resulting mean and 90th percentile intakes of oat oil PL40 by the total U.S. population from proposed food uses in the U.S., were estimated to be 3.6 g/person/day (66 mg/kg body weight/day) and 8.2 g/person/day (146 mg/kg body weight/day), respectively. Among the individual population groups, male adults were determined to have the highest mean and 90th percentile intakes of oat oil PL40 at 4.0 g/person/day (45 mg/kg body weight/day) and 9.6 g/person/day (111 mg/kg body weight/day), respectively. Female teenagers had the lowest mean and 90th percentile consumer-only intakes of 3.0 and 7.0 g/person/day (52 and 112 mg/kg body weight/day), respectively, on an absolute basis. When expressed on a body weight basis, infants and young children had the highest daily mean and 90th percentile intakes, of 286 and 738 mg/kg body weight/day, respectively. Although younger populations were identified as the groups having higher exposures to oat oil PL40 on a body weight basis, the GRAS Panel notes that products containing oat oil PL40 will not serve as their primary source of fat or nutrients in the diet (*e.g.*, baby foods complement milk or infant formula and do not replace it entirely). Estimates described herein assume *all* products, including those consumed by younger individuals, would contain oat oil PL40 at the maximum intended use levels. In actuality, these products would, in the worst case, only be consumed incidentally, and intakes described in the older populations (*i.e.*, not more than 59 and 143 mg/kg body weight/day at the mean and 90th percentile, respectively) are expected to be more accurate estimates of dietary exposure among the intended population.

The GRAS Panel reviewed the data and information on the intended food uses and estimated exposures and concluded that the use of oat oil PL40 will serve as an alternative to existing vegetable oils and any slight changes to the current dietary exposure to fat among U.S. consumers of foods will be clearly reflected on the nutrition facts panel of the food.

INFORMATION TO ESTABLISH THE SAFETY OF OAT OIL PL40

The GRAS Panel critically evaluated the documentation provided by Swedish Oat Fiber containing generally available data and information relevant to the safety of oat oil PL40. The available data included discussions on the natural occurrence of oat oil PL40 in oats which are commonly consumed by humans as part of a normal diet, the history of safe consumption of the constituents in oat oil PL40 (triglycerides, phospholipids, and glycolipids), the metabolic fate of these constituents, safety studies of oat oil PL40 and similar oat oil products in animal models, studies of similar oat oil products in humans which included measures of safety and tolerability, and considerations for immunotoxicity, hypersensitivity, allergy, and food intolerance. Swedish Oat Fiber performed a search of the scientific literature published until July 2019 to obtain new data and information relevant to the safety of oat oil PL40 as a food ingredient. The GRAS Panel also reviewed findings from unpublished toxicological studies (consisting of a 28-day study in Sprague-Dawley rats and a 28-day study in Beagle dogs) and genotoxicity studies (consisting of a bacterial reverse mutation assay and a chromosome aberration test in human blood lymphocytes) with the commercial oat oil PL40 ingredient. These studies were originally commissioned to fulfill regulatory requirements for the authorization of oat oil PL40 as a pharmaceutical excipient and were not published because this was not a requirement for submission at the time. The GRAS Panel understands that all available information pertinent to the safety of a substance must be evaluated as part of a GRAS conclusion but also recognizes that the conclusion itself must be based solely on information within the public domain. The GRAS Panel therefore did not take into consideration the findings from the unpublished studies when they individually and collectively reached their decision concerning the safety of oat oil PL40, although the GRAS Panel does note that the findings from these studies corroborate the safety of oat oil PL40 as no adverse effects or genotoxicity were reported.

Natural Occurrence

The individual constituents of oat oil PL40 are naturally occurring in both oats and other vegetables and vegetable oils. Oat oil PL40 has not been the subject of previous GRAS assessments and has not been previously used in food in the U.S. However, the GRAS Panel noted that Fabuless (also known as Olibra), a commercial vegetable oil emulsion comprised of oat oil and palm oil in a 6:94 ratio is sold in the U.S., Sweden, and Finland, and used in meal replacement beverages, dairy products, and ultra-high temperature processing milk and was introduced into the U.S. market in 1997, with introduction into Sweden and Finland in 2005.

Oat oil PL40 consists of 2 primary classes of lipids: triglycerides (neutral lipids), and polar lipids, which are further subdivided into phospholipids (phosphatidylcholine, phosphatidylglycerol, lyso-phosphatidylglycerol, n-acyl phosphatidylethanolamine, phosphatidylethanolamine, di-acyl-phosphatidylglycerol, and phosphatidic acid) and glycolipids [mono- and digalactosyldiacylglycerol (MGDG; DGDG, respectively), diacylglycerol-diacyl phosphatidylglycerol, and sterylglucoside]. The chemicals within each group are structurally similar to one another and to other substances of the same structural class which are found in common foods. Triglycerides, phospholipids, and glycolipids share common metabolic fates and have the same safety profiles as other substances found in food which reside within the same structural class. Triglycerides and phospholipids are also synthesized in humans to fulfill particular metabolic functions such as energy storage, as cellular membrane transporters and/or receptors, for cell-to-cell aggregation and dissociation, and for brain and eye functions (Brandenburg *et al.*, 2010; Gimenez *et al.*, 2011).

Oats also contain epoxy- and hydroxy- fatty acids at concentrations in the total oil of up to 3.3% and 0.4%, respectively (Leonova *et al.*, 2008). Hydroxy- and epoxy-fatty acids are produced by an endogenous enzymatic process that commonly uses oleic acid as a substrate, although linoleic and linolenic acids may also be used by the oat plant (Leonova *et al.*, 2008; Doehlert *et al.*, 2010; Meesapyodsuk and Qiu, 2011). Hydroxy fatty acids are commonly reported in the polar lipid fraction while epoxy fatty acids are mainly present in the neutral lipid fraction of the total fats (Leonova *et al.*, 2008; Doehlert *et al.*, 2010; Meesapyodsuk and Qiu, 2011). There is evidence that these hydroxy and epoxy fatty acids have been consumed as part of the normal diet, either from oats or from other foods. Beyond dietary occurrence, epoxides of fatty acids have also been reported to be naturally produced in the central and peripheral nervous system *via* cytochrome P450 enzymes (Morisseau *et al.*, 2010). Under the intended conditions of use of oat oil PL40, the estimated exposure to hydroxy- and epoxy- fatty acids is expected to be similar to that from consumption of oats and other commercial edible and frying oils in the normal diet.

The GRAS Panel concludes that the constituents of oat oil PL40 are naturally occurring substances which are commonly found in other foods and that none of these constituents are predicted to give rise to safety concerns under the intended conditions of use.

History of Safe Consumption

Swedish Oat Fiber expressed the estimated consumption of oat oil PL40 in terms of its major constituents (triglycerides, phospholipids, and glycolipids) to discuss the history of safe consumption of oat oil PL40 relative to the consumption of these constituents in the normal diet. Published study reports have noted that individuals consume 50 to 150 g of fatty acids per day while consumers of a typical western diet consume approximately 2 to 8 g of dietary phospholipids (polar lipids) per day (Cohn *et al.*, 2010; Armand, 2013). The estimated mean intakes for lecithin, which contain high concentrations of glycolipids, ranged from 50 to 365 mg/kg body weight/day and the estimated 95th percentile intakes ranged from 109 to 520 mg/kg body weight/day (EFSA, 2017). Based on a glycolipid content of 16% in lecithin, these intakes correspond to intakes of 8 to 58.4 mg glycolipids/kg body weight/day and 17.4 to 83.2 mg glycolipids/kg body weight/day for mean and 95th percentile intakes, respectively, for infants to the elderly (3 months to over 65 years) (EFSA, 2017).

The estimated intake of phospholipids and triglycerides from the intended use of oat oil PL40 among the general population was calculated by Swedish Oat Fiber using the estimated intake of oat oil PL40 under the intended conditions of use and information on the concentration of these constituents in oat oil PL40 (24.0% phospholipids, 19.9% glycolipids, and 56.1% triglycerides). The estimated intake of phospholipids and triglycerides are approximately 0.86 g/day and 2.02 g/day, respectively. Among male adults (the highest consumer group) in the 90th percentile intake group, the estimated intake of phospholipids and triglycerides from the intended uses of oat oil PL40 is 2.3 g/day and 5.39 g/day, respectively. For glycolipids, the mean consumer-only intakes for the total population and 90th percentile consumer-only intakes for the highest and most relevant consumers (male teenagers; see Section 5.3 for justification) from oat oil PL40 were 13.1 and 28.5 mg glycolipid /kg body weight/day, respectively. Swedish Oat Fiber concluded that based on the foregoing, the estimated intakes of triglycerides and phospholipids from the intended uses of oat oil PL40 are less than the amounts estimated to be consumed from other dietary sources (stated above) while the estimated intake of glycolipids from the proposed uses of oat oil PL40 are within the range of the estimated intake from lecithin. The GRAS Panel notes that the background intake of glycolipids calculated from lecithin consumption alone is conservative and does not account for intake of glycolipids from all dietary sources, which is large and difficult to estimate considering its ubiquity in foods. The GRAS Panel therefore concludes that the consumption of oat oil PL40 under the intended conditions of use will result in exposures to triglycerides, phospholipids, or glycolipids which are within the typical range for these

substances from other dietary sources and are not expected to give rise to safety concerns based on their history of safe consumption.

Metabolic Fate and Toxicokinetics

The metabolic fate and toxicokinetics of oat oil PL40 were assessed by Swedish Oat Fiber in terms of the normal metabolic fate of its constituents (triglycerides, phospholipids, and glycolipids) following consumption in the diet. The constituents are expected to exhibit similar metabolic fates to that of other edible vegetable oils and fatty acids derived from common sources. According to the Institute of Medicine (IOM, 2005), when ingested, dietary lipids are hydrolyzed by buccal, gastric, pancreatic and intestinal lipases. Lipases catalyze the breakdown of triglycerides into free fatty acids and acylglycerols. The long chain fatty acid lipids are expected to be digested in the upper portion of the small intestine before the breakdown products are absorbed.

Dietary phospholipids are hydrolyzed *via* pancreatic phospholipase A_2 in the gastrointestinal lumen into lyso-phospholipids which are re-esterified and may be assembled with cholesterol, free fatty acids, glycerols, and apoproteins into lipoproteins. Lipoproteins and lysophospholipids are absorbed through the intestinal mucosal cells through the small intestine and may enter the circulation through the thoracic duct where they are subjected to first-pass metabolism in the liver. Most newly absorbed fatty acids are stored as triacylglycerol in adipose tissue but, when required (*i.e.*, during exercise or fasting states), may by hydrolyzed by hormone-sensitive lipases to free fatty acids which are liberated into the circulation and can be oxidized by skeletal muscles or in the liver. The oxidative process for fatty acids produces only carbon dioxide and water, with small amounts of ketone bodies produced by fatty acid oxidation that may be excreted in the urine (IOM, 2005).

Following ingestion, the glycolipids in oat oil PL40 will be digested by pancreatic enzymes and cleaved into free fatty acids and sugars (galactose, glycerol, fatty acids, phosphate, and plant sterols) which are absorbed from the gastrointestinal lumen and metabolized according to well-established pathways.

A digestibility study evaluating the gastrointestinal and metabolic properties of oat oil, specifically, a vegetable-oil emulsion of oat oil and palm oil (Fabuless[1]), in yogurt was investigated in healthy humans *via* a validated intestinal perfusion technique (Knutson *et al.*, 2010). The study was a randomized, double-blind, placebo-controlled crossover study, wherein subjects consumed the test item and samples were collected from the stomach and prior to the proximal jejunum. Analyses of these samples supported that hydrolysis of the lipids commenced in the stomach and the lipids were almost fully hydrolyzed to free fatty acids by the time they reached the proximal jejunum. The study investigators also reported crystal structures determined to consist of palmitic acid and, according to the investigators, *"The crystallization of hydrolyzed ingested lipids in the gastrointestinal lumen makes it possible that sufficient amounts of lipids may reach the ileum and activate a feedback mechanism, such as an ileal brake"*, which would contribute to increased satiety.

[1] The lipid fraction of Fabuless is comprised of a blend of palm oil and oat oil in a 94:6 ratio.

Toxicological Studies

Subchronic Studies

Oat oil PL40 was evaluated in 28-day oral toxicity studies in Sprague-Dawley rats and Beagle dogs (Saynor, 2003, 2004). These studies were unpublished and are of an insufficient duration to evaluate the safety of oat oil PL40; however, in these studies, no adverse effects were reported, and the findings corroborate the history of safe use of oat oil PL40 which has been established above. In both 28-day oral toxicity studies, no adverse effects were reported and there were no macroscopic or histopathological test item-related findings. The study authors concluded that the no-observed-adverse effect levels (NOAEL) was 5,000 mg/kg body weight/day, the highest dose tested, for both studies. The NOAEL corresponds to a NOAEL of 2,000 mg/kg body weight/day for the polar lipid component of oat oil PL40.

Reproductive and Developmental Studies

Oat oil PL40 is comprised of triglycerides, phospholipids, and glycolipids which are present in the typical diet in similar or greater amounts than the estimated intake of oat oil PL40 under the intended conditions of use. Reproductive and developmental effects are therefore not expected to arise under the intended conditions of use of oat oil PL40. In the unpublished 28-day toxicity studies in rats and dogs (Saynor, 2003, 2004), oat oil PL40 consumption did not produce macroscopic or histological changes in the reproductive organs which were examined.

Genotoxicity Studies

Genotoxicity is not anticipated following consumption of oat oil PL40 under the intended conditions of use based on the composition of the product and the ubiquity of its constituents in the normal diet. Regardless, unpublished *in vitro* genotoxicity studies consisting of a bacterial reverse mutation assay in *Salmonella typhimurium* strains TA98, TA100, TA1535, and TA1537 (Johnson, 2003) and a chromosomal aberration test in cultured human blood lymphocytes (Kumaravel, 2003) were conducted to evaluate the genotoxic potential of oat oil PL40. The *in vitro* chromosomal aberration test is considered a viable alternative to the *in vitro* mammalian cell micronucleus test (which would normally be conducted with the bacterial reverse mutation assay as part of the basic test battery), as it also evaluates clastogenic potential. In both assays, there was no evidence of genotoxicity at up to the highest test concentrations used (5,000 µg/plate and 5,000 µg/mL for the bacterial reverse mutation assay and chromosomal aberration assay, respectively). These genotoxicity studies have not been published due to the owners of the study reports permitting their use but not their publication[2]. Therefore, these genotoxicity studies were only used to corroborate the safety of oat oil PL40 which is supported based on the history of use of the constituents in oat oil PL40.

[2] The study sponsor originally commissioned the studies as part of work to develop oat oil PL40 as a pharmaceutical excipient and was not considering a GRAS submission at the time.

Other Studies

Oat oil preparations have been investigated in mice and rats to examine its potential protective effects against certain pathological states. These studies, although not designed to investigate safety, provide additional support that administration of oat oil is not associated with adverse effects and can mitigate toxicological effects (*e.g.*, testicular biomarkers of toxicity, obesity, formation of pre-neoplastic hepatic lesions) under specific conditions. The oat oils tested in these studies are not oat oil PL40 and would therefore have different ratios of polar lipids to triglycerides. The findings from these large doses are relevant to the safety of oat oil PL40 under the intended conditions of use in food and beverages and are described below.

In a 35-day repeated dose study in male Swiss mice, animals were administered deltamethrin alone or in combination with a hexane-extracted oat oil, or the oat oil alone without deltamethrin to evaluate the effect of oat oil on reproductive parameters (Ben Halima *et al.*, 2014). There were no statistically significant effects of the oat oil on sperm parameters. Co-administration of the oat oil ameliorated testicular biochemical markers of toxicity and the histopathological changes in the testes caused by deltamethrin exposure.

In a 30-day study, the effect of a supercritical carbon dioxide extract from oat fiber was evaluated in Wistar-Lewis rats fed a hypercholesteremic diet supplemented with 70 g/kg diet of the oat extract or soybean oil to evaluate the effect of the extract on diet-induced hypercholesteremia (Tong *et al.*, 2014). There was no statistically significant effect of the oat extract on body weight, body weight gain, food intake, or liver weight relative to the soybean oil control group. Oat extract did reduce total adipose tissue and white adipose tissue sites without any effect on brown adipose tissue, relative to the control group. Liver cholesterol, free cholesterol, cholesterol ester, and liver triglycerides were statistically significantly decreased relative to the control group.

A study on the modulation of liver preneoplastic lesions in which female Sprague-Dawley rats were administered 10% corn oil or 10% oat lipids during a 4-week tumor initiation phase and a 5-month tumor promotion phase (Li *et al.*, 1999). There were no differences in body weight, liver weights, or growth between the oat lipid and corn oil groups. Oat lipid consumption exerted a protective effect against the formation or pre-neoplastic hepatic foci. I-compounds ("indigenous compounds"), an endogenously produced bulky DNA modification which occurs in response to dietary restriction or consumption of certain unprocessed foods, were increased in the oat lipid group. The study investigators in this study and previously (Li *et al.*, 1992) attributed the increase in I-compounds in rats to a sterol present in the oat oil. There is no indication in this study or elsewhere in the literature that suggests these endogenous compounds could form carcinogenic adducts.

Human Studies

Oat oil in Olibra (Fabuless; contains approximately 2% oat oil) was investigated in 10 human studies, discussed below, to evaluate its ability to modify hunger/satiety, food intake, body composition, and/or palatability. These studies also included observations for reports of adverse effects and, in some studies, analysis of blood samples for hematological or clinical chemistry markers of organ function.

Three single-dose crossover studies were conducted by Burns *et al.* (2000, 2001, 2002) to evaluate the effect of Olibra at doses of 5 to 15 g on energy intake and feelings of hunger up to 8 hours post-administration. Subjects did not report any ill effects or discomfort following consumption of Olibra; however, the GRAS Panel noted that the study authors did not clearly describe how adverse effects were monitored or for how long after consumption of the test article. In all 3 studies, all of the subjects returned to cross over to the next study arm which implied that had any ill effect occurred and were not captured, they were not of a severe enough to make the subjects drop out.

In a separate single-dose study, healthy male subjects consumed 8.5 g milk fat (control) or 8.5 g Olibra in yogurt to evaluate the effect of the treatments on orocecal transit time using a marker (Haenni *et al.*, 2009). There were no adverse events reported during the study or the follow-up visit. Orocecal transit time was prolonged in the Olibra group and considered to be due to an ileal brake mechanism that slows gastrointestinal transit time. Knutson *et al.* (2010) investigated the effect of the same dose levels of Olibra on fatty acid concentrations in the proximal jejunum and found that they were increased relative to the milk fat control group, again supporting an ileal brake mechanism.

When male and female subjects were provided a yogurt-based meal replacement drinking containing 5 g milk fat and corn oil (control), 12.5 g Olibra (5 g fat added during manufacture), or 12.5 g Olibra (5 g fat added after manufacture) in a single dose study, there were no differences between the groups in terms of adverse physical symptoms, palatability scores, mood ratings, or measures of appetite (Smit *et al.*, 2011). Energy intake was statistically significantly reduced only among subjects in the Olibra group with fat added after manufacture (relative to the control group).

In a 3-week study, 28 subjects were provided 200 g of yogurt with 5 g milk fat (control) or 5 g Olibra per day (Logan *et al.*, 2006). There were no significant effects of Olibra on body weight or anthropometric measures and no subjects dropped from the study for test article-related reasons. There was a statistically significant decrease in mean fasting blood glucose in males relative to the control group, although the clinical significance of this finding is unclear according to the study investigator.

There were no effects of an Olibra emulsion (15 g; 4.2 g lipid) on organoleptic properties (pleasantness, visual appeal, smell, taste, palatability) in a test yogurt or muffin when compared to a yogurt or muffin containing a palm olein emulsion (control) in a single dose palatability study (Chan *et al.*, 2012). Differences were reported when the emulsion was added to water and compared against water alone. Subjects reported increased feeling of fullness when Olibra was provided with yogurt, but not with the muffin or water. There were no significant differences in eating behavior. The study authors indicated that adverse events, if any, were recorded and a discussion on nausea monitoring was outlined. The authors did not provide any findings concerning adverse events, implying by omission that these did not arise in the study.

In a single-dose study, subjects consumed in the first phase yogurt with 35 g milk fat (control) or oat oil lipids and in the second phase, yogurt with 35 g milk fat (control), 14 g oat oil lipids with 21 g milk fat, or 1.8 g oat oil lipids with 33.2 g milk fat (Ohlsson *et al.*, 2014). Subjects reported that 14 g oat lipids were not very palatable and there were reports of discomfort in the gut in the first few hours after exposure. There were statistically significant reductions in plasma postprandial cholecystokinin, glucagon-like peptides 1 and 2, and peptide YY in the 14 g and 35 g oat oil lipid groups. Energy intake was also reduced among women that consumed the yogurt containing 35 g oat oil lipids; however, the effect was not statistically significant. These findings suggest that adverse effects following consumption of large amounts of oat oil, many times greater than the intended use level of oat oil PL40, results in minor, transient gastrointestinal disturbances and changes in postprandial blood biomarkers indicative of a lower glycemic state. The GRAS Panel did not consider these findings to be adverse.

A study among 50 overweight female subjects was performed wherein they first took part in a 6-week weight loss diet program followed by an 18-week weight maintenance program (Diepvens *et al.*, 2007). During the weight maintenance phase, subjects consumed yogurt containing 5 g milk fat (control) or 5 g Olibra (providing 3 g milk fat and 2 g vegetable fat) twice daily. There were no significant differences in tolerance or measured blood parameters between the 2 groups. The subjects in the Olibra group were able to maintain the weight loss, reduced body mass index, and waist circumference from the weight loss phase, whereas subjects in the control group increased those parameters.

Overall, there were no statistically significant adverse effects attributable to consumption of Olibra where the highest dose tested was 6 g/day (equivalent to 0.12 g oat oil/day) and the longest treatment period was 4 months. The GRAS Panel agrees that these studies support the safety of oat oil in the diet under the intended conditions of use.

Immunotoxicity, Hypersensitivity, Allergy, and Food Intolerance

Oat oil PL40, a refined plant oil, is not anticipated to be a risk of allergenicity or hypersensitivity beyond that of oats themselves and will not present a greater allergenic risk than similar products produced from soya or egg. According to Crevel *et al.* (2000), vegetable-derived oils demonstrate very little allergenic risk. Swedish Oat Fiber has Evaluations of oat oil PL40 for gluten demonstrate that gluten concentrations are well below the 20 mg/kg limit for labelling food as gluten-free and is not expected to present a tolerance issue among persons with celiac disease or gluten intolerance (21 CFR §101.91 – U.S. FDA, 2018a).

SUMMARY

We, the members of the GRAS Panel, have, independently and collectively, critically evaluated the data and information summarized above that is pertinent to the safety of the proposed use of oat oil PL40. We unanimously conclude that oat oil PL40 as manufactured by Swedish Oat Fiber, meeting appropriate food-grade specifications and produced in accordance with current good manufacturing practice (cGMP), is Generally Recognized as Safe (GRAS) based on scientific procedures under the conditions of intended use in foods and beverages specified herein, including standardized chocolate.

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

[redacted]

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REFERENCES

Armand M (2013). Stratégies de contrôle de la biodisponibilité des lipides. Dans: Fardet A, Souchon I, Dupont D, editors. *Structure des Aliments et Effets Nutritionnels [Food Structure and Nutritional Effects]*. Paris, France: QUAE, pp. 373–413.

Ben Halima N, Ben Slima A, Moalla I, Fetoui H, Pichon C, Gdoura R, et al. (2014). Protective effects of oat oil on deltamethrin-induced reprotoxicity in male mice. Food Funct 5(9):2070-2077. DOI:10.1039/c4fo00190g.

Brandenburg K, Garidel P, Gutsmann T (2010). Physicochemical properties of microbial glycopolymers. In: Holst O, Brennan PJ, von Itzstein M, editors. *Microbial Glycobiology: Structures, Relevance and Applications*. San Diego (CA): Academic Press, pp. 759-779.

Burns AA, Livingstone MB, Welch RW, Dunne A, Robson PJ, Lindmark L et al. (2000). Short-term effects of yoghurt containing a novel fat emulsion on energy and macronutrient intakes in non-obese subjects. Int J Obesity Relat Metab Disord 24(11):1419-1425. DOI:10.1038/sj.ijo.0801430.

Burns AA, Livingstone MB, Welch RW, Dunne A, Reid CA, Rowland IR (2001). The effects of yoghurt containing a novel fat emulsion on energy and macronutrient intakes in non-overweight, overweight and obese subjects. Int J Obesity Relat Metab Disord 25(10):1487-1496. DOI:10.1038/sj.ijo.0801720.

Burns AA, Livingstone MB, Welch RW, Dunne A, Rowland IR (2002). Dose-response effects of a novel fat emulsion (Olibra™) on energy and macronutrient intakes up to 36 h post-consumption. Eur J Clin Nutr 56(4):368-377. DOI:10.1038/sj.ejcn.1601326.

Chan Y-K, Strik CM, Budgett SC, Mcgill A-T, Proctor J, Poppitt SD (2012). The emulsified lipid Fabuless (Olibra) does not decrease food intake but suppresses appetite when consumed with yoghurt but not alone or with solid foods: a food effect study. Physiol Behav 105(3):742-748. DOI:10.1016/j.physbeh.2011.08.042.

Cohn JS, Kamili A, Wat E, Chung RW, Tandy S (2010). Dietary phospholipids and intestinal cholesterol absorption. Nutrients 2(2):116-127. DOI:10.3390/nu2020116.

Crevel RW, Kerkhoff MA, Koning MM (2000). Allergenicity of refined vegetable oils. Food Chem Toxicol 38(4):385-393. DOI:10.1016/S0278-6915(99)00158-1.

Diepvens K, Soenen S, Steijns J, Arnold M, Westerterp-Plantenga M (2007). Long-term effects of consumption of a novel fat emulsion in relation to body-weight management. Int J Obes (Lond) 31(6):942-949. DOI:10.1038/sj.ijo.0803532.

Doehlert DC, Moreau RA, Welti R, Roth MR, McMjullen MS (2010). Polar lipids from oat kernels. Cereal Chem 87(5):467-474. DOI:10.1094/CCHEM-04-10-0060.

EFSA (2017). Scientific opinion on the re-evaluation of lecithins (E 322) as a food additive. (EFSA Panel on Food Additives and Nutrient Sources added to Food/ANS) (Question no EFSA-Q-2011-00500, adopted: 1 March 2017 by European Food Safety Authority). EFSA J 15(4):4742 [74pp]. DOI:10.2903/j.efsa.2017.4742. Available at: https://www.efsa.europa.eu/en/efsajournal/pub/4742.

Gimenez MS, Oliveros LB, Gomez NN (2011). Nutritional deficiencies and phospholipid metabolism. Int J Mol Sci 12(4):2408-2433. DOI:10.3390/ijms12042408.

Haenni A, Sundberg B, Yazdanpandah N, Viberg A, Olsson J (2009). Effect of fat emulsion (Fabuless) on orocecal transit time in healthy men. Scand J Gastroenterol 44(10):1186-1190. DOI:10.1080/00365520903131999.

IOM (2005). Dietary fats: total fat and fatty acids. In: *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids (Macronutrients)*. (National Academy of Sciences/NAS, Institute of Medicine/IOM, Food and Nutrition Board/FNB, Panel on Micronutrients, Panel on the Definition of Dietary Fiber, Subcommittee on Upper Reference Levels of Nutrients, Subcommittee on Interpretation and Uses of Dietary Reference Intakes, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes). Washington (DC): National Academy Press (NAP), pp. 422-541. Available at: http://www.nap.edu/openbook.php?record_id=10490&page=422.

Johnson M (2003) [unpublished]. *Study Title: Oat Lecithin, FOO: Reverse Mutation in Five Histidine-Requiring Strains of Salmonella typhimurium. [Confidential]*. (Covance Study Number: 2213/7; Covance Report Number: 2213/7-D6171; Dated: September 2003). North Yorkshire, UK: Covance Laboratories Ltd.

Knutson L, Koenders DJ, Fridblom H, Viberg A, Sein A, Lennernäs H (2010). Gastrointestinal metabolism of a vegetable-oil emulsion in healthy subjects. Am J Clin Nutr 92(3):515-524. DOI:10.3945/ajcn.2009.28941.

Kumaravel TS (2003) [unpublished]. *Study Title: Oat Lecithin, FOO: Induction of Chromosome Aberrations in Cultured Human Peripheral Blood Lymphocytes [Confidential]*. (Covance Study Number: 2213/8; Covance Report Number: 2213/8-D6172; Dated: December 2003). North Yorkshire, UK: Covance Laboratories Ltd.

Leonova S, Shelenga T, Hamberg M, Konarev AV, Loskutov I, Carlsson AS (2008). Analysis of oil composition in cultivars and wild species of oat (*Avena* sp.). J Agric Food Chem 56(17):7983-7991. DOI:10.1021/jf800761c.

Li D, Chen S, Randerath K (1992). Natural dietary ingredients (oats and alfalfa) induce covalent DNA modifications (I-compounds) in rat liver and kidney. Nutr Cancer 17(3):205-216. DOI:10.1080/01635589209514189.

Li D, Wang M, Paul GP, Pitot HC, Dragan Y (1999). Dietary oat lipids-induced novel DNA modifications and suppression of altered hepatic foci formation. Nutr Cancer 33(1):40-45. DOI:10.1080/01635589909514746.

Logan CM, McCaffrey TA, Wallace JM, Robson PJ, Welch RW, Dunne A, et al. (2006). Investigation of the medium-term effects of Olibratrade mark fat emulsion on food intake in non-obese subjects. Eur J Clin Nutr 60(9):1081-1091. DOI:10.1038/sj.ejcn.1602422.

Meesapyodsuk D, Qiu X (2011). A peroxygenase pathway involved in the biosynthesis of epoxy fatty acids in oat. Plant Physiol 157(1):454-463. DOI:10.1104/pp.111.178822.

Morisseau C, Inceoglu B, Schmelzer K, Tsai HJ, Jinks SL, Hegedus CM, et al. (2010). Naturally occurring monoepoxides of eicosapentaenoic acid and docosahexaenoic acid are bioactive antihyperalgesic lipids. J Lipid Res 51(12):3481-3490 [plus supplementary data]. DOI:10.1194/jlr.M006007.

Ohlsson L, Rosenquist A, Rehfeld JF, Härröd M (2014). Postprandial effects on plasma lipids and satiety hormones from intake of liposomes made from fractionated oat oil: two randomized crossover studies. Food Nutr Res 58 [11pp.]. DOI:10.3402/fnr.v58.24465.

Saynor S (2003) [unpublished]. *Study Title: Oat Lecithin (FOO): 28 Day Oral (Gavage) Administration Toxicity Study in the Rat [Confidential]*. (Covance Study Number: 2213/005; Dated: November 2003). North Yorkshire, UK: Covance Laboratories Ltd.

Saynor S (2004) [unpublished]. *Study Title: Oat Lecithin (FOO): 28 Day (Gavage) Administration Toxicity Study in the Dog [Confidential]*. (Covance Study No: 2213/006; Dated: March 2004). North Yorkshire, UK: Covance Laboratories Ltd.

Smit HJ, Keenan E, Kovacs EMR, Wiseman SA, Peters HPF, Mela DJ, et al. (2011). No efficacy of processed Fabuless (Olibra) in suppressing appetite or food intake. Eur J Clin Nutr 65(1):81-86. DOI:10.1038/ejcn.2010.187.

Tong L-T, Zhong K, Liu L, Guo L, Cao L, Zhou S (2014). Oat oil lowers the plasma and liver cholesterol concentrations by promoting the excretion of faecal lipids in hypercholesterolemic rats. Food Chem 142:129-134. DOI:10.1016/j.foodchem.2013.07.028.

U.S. FDA (2018a). Part 101—Food labeling. §101.91—Gluten-free labeling of food. In: U.*S. Code of Federal Regulations (CFR). Title 21—Food and Drugs*. (Food and Drug Administration). Washington (DC): U.S. Government Printing Office (GPO). Available at: https://www.govinfo.gov/app/collection/cfr/2018/title21

U.S. FDA (2018b). 170—Food additives. §170.3—Definitions. In: U.*S. Code of Federal Regulations (CFR). Title 21—Food and Drugs*. (Food and Drug Administration). Washington (DC): U.S. Government Printing Office (GPO). Available at: https://www.govinfo.gov/app/collection/cfr/2018/title21.

Attachment A Intended Uses and Use Levels for Oat Oil PL40

Table A-1 Summary of the Individual Proposed Food Uses and Use Levels for Oat Oil in the U.S.

Food Category (21 CFR §170.3) (U.S. FDA, 2018b)	Food Uses	Oat Oil Use Levels (g/100 g)
Infant Formula and Baby Food	Baby food: Cereals	2.0
	Baby food: Dinners, Desserts, Fruits, Vegetables, or Soups	2.0
	Baby food: Ready-to-Eat Cereals, Cookies, Teething Biscuits, and Toasts	2.0
Baked Goods and Baking Mixes	Pan or Flat Bread Product	2.0
Beverages and Beverage Bases	Cocoa and/or Malted Beverages	2.0
	Flavored or Carbonated Waters	0.8
	Non-Milk-Based Meal Replacement Beverages	2.0
	Protein Drinks	2.0
	Sport or Electrolyte Drinks, Fluid Replacement Drinks	0.2
Breakfast Cereals	Instant Hot Breakfast Cereals	2.0
	Ready-to-Eat Breakfast Cereals	2.0
Coffee and Tea	Combined Coffee and Whitener Products	2.0
	Specialty Coffee Drinks (Lattes, Cappuccinos, Mochas)	2.0
Dairy Product Analogs	Non-Dairy Based Ambient and Chilled Dessert *e.g.*, mousse	2.0
	Non-Dairy Culinary Cooking Creams Sauces	2.0
	Non-Dairy Milk, Cream, and Coffee/Tea Whiteners	2.0
Fats and Oils	Margarine, and Margarine-Like Spreads	2.0
	Mayonnaise and Mayonnaise-Type Dressings	2.0
	Oils	2.0
	Salad Dressings	2.0
Frozen Dairy Desserts	Frozen Yogurt (Frozen Yoghurt)	2.0
	Ice Cream	2.0
	Other Frozen Milk Desserts	2.0
Grain Products and Pastas	Cereal and Granola Bars	2.0
	Energy Bars or Protein Bars	2.0
	Meal Replacement Bars	2.0
Milk Products	Culinary Cooking Creams Sauces	2.0
	Dairy Based Chilled or Ambient Dessert *e.g.*, mousse	2.0
	Flavored Milk, Milk Drinks, and Mixes	2.0
	Milk Shakes	2.0
	Milk-Based Meal Replacements	2.0
	Nutritional Supplement Meal Replacements	2.0
	Plain or Flavored Yogurt (Yoghurt)	2.0
Plant Protein Products	Meat Analogs	2.0
Snack Foods	Extruded and/or Expanded Materials for Humans for Example Extruded Snacks	2.0
Soft Candy	Chocolate	2.0
	Nougat and Toffees	2.0

CFR = Code of Federal Regulations; RACC = Reference Amounts Customarily Consumed per Eating Occasion; U.S. = United States.

APPENDIX B
Certificates of Analysis

NAME
SWEOAT Oil PL40

PRODUCT CODE
0066.03.0040

DESCRIPTION
An oat oil with a yellowish brown colour and oat cereal taste. Contains natural antioxidants and is rich in polar lipids (phospho- and galactolipids)

CERTIFICATE OF ANALYSIS

BATCH #	MANUFACTURE DATE
PL40-20170102	6-Jan-2017
ORDER # CUSTOMER	ANALYSIS DATE
	9-Jan-2017
ORDER # SOF	BEST BEFORE DATE
	8-Jul-2018

ITEM	STANDARD	RESULT	METHOD
Sensorial characteristics	Oat cereal taste.	Complies	Sensorial
Appearance	Oil with a yellowish brown colour	Complies	Visual
Polar lipids	>35%	44,0%	Internal method
Water	<2%	0,3%	Karl Fischer
[1]Ethanol residue	<500ppm	59ppm	16 M 54 5141 9 GC-FID
Acid value	<30mg KOH/g	NA	Metler Toledo application, M621-2012
Peroxide value	<10 meq O_2/kg fat	1,8%	Metler Toledo application, M624-2012
[1] Moulds	< 100 cfu/g	Complies	NMKL98,2005
[1]Yeast	< 100 cfu/g	Complies	NMKL98,2005
[1]Aerobic plate count	< 1000 cfu/g	Complies	3M 01/01-09/89
[1]Enterobacteriaceae	< 10 cfu/g	Complies	NMKL 144
[1]Aerobic spores	<1 cfu/g	Complies	Internal method
[2]Mycotoxins	According to EU regulation 1881/2006	Complies	LC-MS/MS
[2]Pesticide residues	According to EU regulation 396/2005	Complies	SLVM917, SLVK1f4m016.1

[1] Spot checks of batches

[2] Spot checks when we start using new harvest

Date
9-Jan-2017

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Org.nr: 556509-0148
VAT No: 556509014801

NAME
SWEOAT Oil PL40

PRODUCT CODE
0066.03.0040

DESCRIPTION
An oat oil with a yellowish brown colour and oat cereal taste. Contains natural antioxidants and is rich in polar lipids (phospho- and galactolipids)

CERTIFICATE OF ANALYSIS

BATCH #	MANUFACTURE DATE
40FG-20170426	28-Apr-2017
ORDER # CUSTOMER	ANALYSIS DATE
	1-May-2017
ORDER # SOF	BEST BEFORE DATE
	28-Oct-2018

ITEM	STANDARD	RESULT	METHOD
Sensorial characteristics	Oat cereal taste.	Complies	Sensorial
Appearance	Oil with a yellowish brown colour	Complies	Visual
Polar lipids	>35%	44,8%	Internal method
Water	<2%	0,3%	Karl Fischer
[1]Ethanol residue	<500ppm	Complies	16 M 54 5141 9 GC-FID
Acid value	<30mg KOH/g	9,8%	Metler Toledo application, M621-2012
Peroxide value	<10 meq O_2/kg fat	0,3%	Metler Toledo application, M624-2012
[1] Moulds	< 100 cfu/g	Complies	NMKL98,2005
[1]Yeast	< 100 cfu/g	Complies	NMKL98,2005
[1]Aerobic plate count	< 1000 cfu/g	Complies	3M 01/01-09/89
[1]Enterobacteriaceae	< 10 cfu/g	Complies	NMKL 144
[1]Aerobic spores	<1 cfu/g	Complies	Internal method
[2]Mycotoxins	According to EU regulation 1881/2006	Complies	LC-MS/MS
[2]Pesticide residues	According to EU regulation 396/2005	Complies	SLVM917, SLVK1f4m016.1

[1] Spot checks of batches

[2] Spot checks when we start using new harvest

Date
1-May-2017

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NAME
SWEOAT Oil PL40

PRODUCT CODE
0066.03.0040

DESCRIPTION
An oat oil with a yellowish brown colour and oat cereal taste. Contains natural antioxidants and is rich in polar lipids (phospho- and galactolipids)

CERTIFICATE OF ANALYSIS

BATCH #
PL40-20170106

ORDER # CUSTOMER

ORDER # SOF

MANUFACTURE DATE
10-Jan-2017

ANALYSIS DATE
13-Jan-2017

BEST BEFORE DATE
12-Jul-2018

ITEM	STANDARD	RESULT	METHOD
Sensorial characteristics	Oat cereal taste.	Complies	Sensorial
Appearance	Oil with a yellowish brown colour	Complies	Visual
Polar lipids	>35%	41,9%	Internal method
Water	<2%	0,3%	Karl Fischer
[1]Ethanol residue	<500ppm	79,4ppm	16 M 54 S141 9 GC-FID
Acid value	<30mg KOH/g	NA	Metler Toledo application, M621-2012
Peroxide value	<10 meq O_2/kg fat	1,1%	Metler Toledo application, M624-2012
[1] Moulds	< 100 cfu/g	Complies	NMKL98,2005
[1]Yeast	< 100 cfu/g	Complies	NMKL98,2005
[1]Aerobic plate count	< 1000 cfu/g	Complies	3M 01/01-09/89
[1]Enterobacteriaceae	< 10 cfu/g	Complies	NMKL 144
[1]Aerobic spores	<1 cfu/g	Complies	Internal method
[2]Mycotoxins	According to EU regulation 1881/2006	Complies	LC-MS/MS
[2]Pesticide residues	According to EU regulation 396/2005	Complies	SLVM917, SLVK1f4m016.1

[1] Spot checks of batches

[2] Spot checks when we start using new harvest

Date
13-Jan-2017

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NAME
SWEOAT Oil PL40

PRODUCT CODE
0066.03.0040

DESCRIPTION
An oat oil with a yellowish brown colour and oat cereal taste. Contains natural antioxidants and is rich in polar lipids (phospho- and galactolipids)

CERTIFICATE OF ANALYSIS

BATCH #
40FO-071216

ORDER # CUSTOMER

ORDER # SOF

MANUFACTURE DATE
16-Dec-2016

ANALYSIS DATE
19-Dec-2016

BEST BEFORE DATE
17-Jun-2018

ITEM	STANDARD	RESULT	METHOD
Sensorial characteristics	Oat cereal taste.	Complies	Sensorial
Appearance	Oil with a yellowish brown colour	Complies	Visual
Polar lipids	>35%	44,7%	Internal method
Water	<2%	0,7%	Karl Fischer
[1]Ethanol residue	<500ppm	79,1ppm	16 M 54 5141 9 GC-FID
Acid value	<30mg KOH/g	9,8%	Metler Toledo application, M621-2012
Peroxide value	<10 meq O_2/kg fat	0,5%	Metler Toledo application, M624-2012
[1] Moulds	< 100 cfu/g	Complies	NMKL98,2005
[1]Yeast	< 100 cfu/g	Complies	NMKL98,2005
[1]Aerobic plate count	< 1000 cfu/g	Complies	3M 01/01-09/89
[1]Enterobacteriaceae	< 10 cfu/g	Complies	NMKL 144
[1]Aerobic spores	<1 cfu/g	Complies	Internal method
[2]Mycotoxins	According to EU regulation 1881/2006	Complies	LC-MS/MS
[2]Pesticide residues	According to EU regulation 396/2005	Complies	SLVM917, SLVK1f4m016.1

[1] Spot checks of batches

[2] Spot checks when we start using new harvest

Date
19-Dec-2016

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NAME
SWEOAT Oil PL40

PRODUCT CODE
0066.03.0040

DESCRIPTION
An oat oil with a yellowish brown colour and oat cereal taste. Contains natural antioxidants and is rich in polar lipids (phospho- and galactolipids)

CERTIFICATE OF ANALYSIS

BATCH #
40FO-131216

ORDER # CUSTOMER

ORDER # SOF

MANUFACTURE DATE
22-Dec-2016

ANALYSIS DATE
25-Dec-2016

BEST BEFORE DATE
23-Jun-2018

ITEM	STANDARD	RESULT	METHOD
Sensorial characteristics	Oat cereal taste.	Complies	Sensorial
Appearance	Oil with a yellowish brown colour	Complies	Visual
Polar lipids	>35%	42,4%	Internal method
Water	<2%	0,2%	Karl Fischer
[1]Ethanol residue	<500ppm	54,9ppm	16 M 54 5141 9 GC-FID
Acid value	<30mg KOH/g	NA	Metler Toledo application, M621-2012
Peroxide value	<10 meq O_2/kg fat	2,5%	Metler Toledo application, M624-2012
[1] Moulds	< 100 cfu/g	Complies	NMKL98,2005
[1]Yeast	< 100 cfu/g	Complies	NMKL98,2005
[1]Aerobic plate count	< 1000 cfu/g	Complies	3M 01/01-09/89
[1]Enterobacteriaceae	< 10 cfu/g	Complies	NMKL 144
[1]Aerobic spores	<1 cfu/g	Complies	Internal method
[2]Mycotoxins	According to EU regulation 1881/2006	Complies	LC-MS/MS
[2]Pesticide residues	According to EU regulation 396/2005	Complies	SLVM917, SLVK1f4m016.1

[1] Spot checks of batches

[2] Spot checks when we start using new harvest

Date
25-Dec-2016

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AR-17-SB-070825-01

EUSEJO2-00256131

Client code:: LW1000416

Reference:
006-10511-134525

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ANALYTICAL REPORT

Sample code:	**527-2017-11150359**
Client Sample:	PL40-20170102
Received:	2017-11-15
Report finished:	2017-11-23
Start of analysis	2017-11-16 13:41
Client sample code	PL40-20170102

	Analysis	Result Unit	Num	Method	Lab
UMF50	Aerobic Plate Count 30°C	< **3.0** log cfu/g	< 1000	3M 01/01-09/89	*EUSEJO2*
UMD53	Enterobacteriaceae 37°C	< **1.0** log cfu/g	< 10	NMKL 144	*EUSEJO2*
UMN88	Yeast	< **2.0** log cfu/g	< 100	NMKL 98	*EUSEJO2*
UMP73	Moulds	< **2.0** log cfu/g	< 100	NMKL 98	*EUSEJO2*
UMY2U *	Spore-forming Aerobic Mesophilic Count	< **1** cfu/g		Internal Method	*EUSEJO2*

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Test was performed by

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Symbol description:
* Not accredited

AR-002 MI v61

Uncert: Measurement uncertainty

Measurement uncertainty, unless otherwise stated, are reported as expanded uncertainty with coverage factor 2. Exceptions related to analysis performed outside Sweden may occur. Additional information can be obtained upon request.

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Reference:
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ANALYTICAL REPORT

Sample code:	**527-2017-11150360**
Client Sample:	PL40-20170106
Received:	2017-11-15
Report finished:	2017-11-23
Start of analysis	2017-11-16 13:41
Client sample code	PL40-20170106

	Analysis	Result Unit	Num	Method	Lab
UMF50	Aerobic Plate Count 30°C	< **3.0** log cfu/g	< 1000	3M 01/01-09/89	*EUSEJO2*
UMD53	Enterobacteriaceae 37°C	< **1.0** log cfu/g	< 10	NMKL 144	*EUSEJO2*
UMN88	Yeast	< **2.0** log cfu/g	< 100	NMKL 98	*EUSEJO2*
UMP73	Moulds	< **2.0** log cfu/g	< 100	NMKL 98	*EUSEJO2*
UMY2U *	Spore-forming Aerobic Mesophilic Count	< **1** cfu/g		Internal Method	*EUSEJO2*

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Client code:: LW1000416

Reference:
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ANALYTICAL REPORT

Sample code:	**527-2017-11150361**
Client Sample:	40FO-071216
Received:	2017-11-15
Report finished:	2017-11-23
Start of analysis	2017-11-16 13:41
Client sample code	40FO-071216

	Analysis	Result	Unit	Num	Method	Lab
UMF50	Aerobic Plate Count 30°C	**< 3.0**	log cfu/g	< 1000	3M 01/01-09/89	*EUSEJO2*
UMD53	Enterobacteriaceae 37°C	**< 1.0**	log cfu/g	< 10	NMKL 144	*EUSEJO2*
UMN88	Yeast	**< 2.0**	log cfu/g	< 100	NMKL 98	*EUSEJO2*
UMP73	Moulds	**< 2.0**	log cfu/g	< 100	NMKL 98	*EUSEJO2*
UMY2U *	Spore-forming Aerobic Mesophilic Count	**< 1**	cfu/g		Internal Method	*EUSEJO2*

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Emma Berglind, ASM
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Test was performed by

EUSEJO2 Eurofins Food & Feed Testing Sweden (Jönköping)

The laboratory/laboratories are accredited by the respective national accreditation body. Non-accredited tests are marked *.

Symbol description:
* Not accredited

AR-002 MI v61

Uncert: Measurement uncertainty

Measurement uncertainty, unless otherwise stated, are reported as expanded uncertainty with coverage factor 2. Exceptions related to analysis performed outside Sweden may occur. Additional information can be obtained upon request.

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AR-17-SB-070828-01

EUSEJO2-00256131

Client code:: LW1000416

Reference:
006-10511-134525

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ANALYTICAL REPORT

Sample code:	**527-2017-11150362**
Client Sample:	40FO-131216
Received:	2017-11-15
Report finished:	2017-11-23
Start of analysis	2017-11-16 08:44
Client sample code	40FO-131216

	Analysis	Result Unit	Num	Method	Lab
UMF50	Aerobic Plate Count 30°C	< **3.0** log cfu/g	< 1000	3M 01/01-09/89	*EUSEJO2*
UMD53	Enterobacteriaceae 37°C	< **1.0** log cfu/g	< 10	NMKL 144	*EUSEJO2*
UMN88	Yeast	< **2.0** log cfu/g	< 100	NMKL 98	*EUSEJO2*
UMP73	Moulds	< **2.0** log cfu/g	< 100	NMKL 98	*EUSEJO2*
UMY2U *	Spore-forming Aerobic Mesophilic Count	< **1** cfu/g		Internal Method	*EUSEJO2*

Copy to:
Pia Waldefelt (p.w@sweoat.se)

Emma Berglind, ASM
Contact: mikro.asm@eurofins.se

This test report has been created electronically and has been verified and authorised.

Test was performed by

EUSEJO2 Eurofins Food & Feed Testing Sweden (Jönköping)

The laboratory/laboratories are accredited by the respective national accreditation body. Non-accredited tests are marked *.

Symbol description:
* Not accredited

Uncert: Measurement uncertainty

AR-002 MI v61

Measurement uncertainty, unless otherwise stated, are reported as expanded uncertainty with coverage factor 2. Exceptions related to analysis performed outside Sweden may occur. Additional information can be obtained upon request.

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Rapport utfärdad av ackrediterat laboratorium

Report issued by Accredited Laboratory

SWEDAC ACKREDITERING 1977 ISO/IEC 17025

Eurofins Food & Feed Testing Sweden (Lidköping)
Box 887
Sjöhagsg. 3
SE-53119 Lidköping
www.eurofins.se

Swedish Oat Fiber
Ellen Hedrén
Båtafjordsvägen 12
432 63 BUA

AR-17-LW-064973-01

EUSELI-00177469

Client code:: LW1000416

Reference:
006-10511-134530

ANALYTICAL REPORT

Sample code:	**525-2017-11170024**
Client Sample:	PL40-20170102
Received:	2017-11-17
Report finished:	2017-11-29
Client sample code	PL40-20170102
Start of analysis	2017-11-17

		Analysis	Result	MRL	Unit	Uncert.	Method	Lab
SL403		Lead (Pb)	**< 0.040**		mg/kg	± 25%	NMKL No 161 1998 mod	*EUSELI2*
SL404		Cadmium (Cd)	**< 0.020**		mg/kg	± 25%	NMKL No 161 1998 mod	*EUSELI2*
J5012		Deoxynivalenol (Vomitoxin)	**<20**		µg/kg		Internal method	*EUHAWE3*
LP152	*	Ethanol	**59.0**		mg/kg	± 10%	Internal Method - GC-FID	*EUSELI*

LP110: No pesticide residue detected (NMKL 195 mod.).

Copy to:
Pia Waldefelt (p.w@sweoat.se)

Mariana Eriksson, ASM

This test report has been created electronically and has been verified and authorised.

Test was performed by

EUHAWE3	Eurofins WEJ Contaminants GmbH (Hamburg)
EUSELI	Eurofins Food & Feed Testing Sweden (Lidköping)
EUSELI2	Eurofins Environment Sweden, Lidköping

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Symbol description:
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AR-004 v27

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Performing laboratory if nothing else is stated: Eurofins Food & Feed Testing Sweden (Lidköping)

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Report issued by Accredited Laboratory

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Swedish Oat Fiber
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432 63 BUA

AR-17-LW-064974-01

EUSELI-00177469

Client code:: LW1000416

Reference:
006-10511-134530

ANALYTICAL REPORT

Sample code:	**525-2017-11170026**
Client Sample:	PL40-20170106
Received:	2017-11-17
Report finished:	2017-11-29
Client sample code	PL40-20170106
Start of analysis	2017-11-17

		Analysis	Result	MRL	Unit	Uncert.	Method	Lab
SL403		Lead (Pb)	**< 0.040**		mg/kg	± 25%	NMKL No 161 1998 mod	*EUSELI2*
SL404		Cadmium (Cd)	**< 0.020**		mg/kg	± 25%	NMKL No 161 1998 mod	*EUSELI2*
J5012		Deoxynivalenol (Vomitoxin)	**<20**		µg/kg		Internal method	*EUHAWE3*
LP152	*	Ethanol	**79.4**		mg/kg	± 10%	Internal Method - GC-FID	*EUSELI*

LP110: No pesticide residue detected (NMKL 195 mod.).

Copy to:
Pia Waldefelt (p.w@sweoat.se)

Mariana Eriksson, ASM

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Test was performed by

EUHAWE3	Eurofins WEJ Contaminants GmbH (Hamburg)
EUSELI	Eurofins Food & Feed Testing Sweden (Lidköping)
EUSELI2	Eurofins Environment Sweden, Lidköping

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AR-004 v27

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Performing laboratory if nothing else is stated: Eurofins Food & Feed Testing Sweden (Lidköping)

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432 63 BUA

AR-17-LW-064975-01

EUSELI-00177469

Client code:: LW1000416

Reference:
006-10511-134530

ANALYTICAL REPORT

Sample code:	**525-2017-11170027**
Client Sample:	40FO-071216
Received:	2017-11-17
Report finished:	2017-11-29
Client sample code	40FO-071216
Start of analysis	2017-11-17

		Analysis	Result	MRL	Unit	Uncert.	Method	Lab
SL403		Lead (Pb)	**< 0.040**		mg/kg	± 25%	NMKL No 161 1998 mod	*EUSELI2*
SL404		Cadmium (Cd)	**< 0.020**		mg/kg	± 25%	NMKL No 161 1998 mod	*EUSELI2*
J5012		Deoxynivalenol (Vomitoxin)	**<20**		µg/kg		Internal method	*EUHAWE3*
LP152	*	Ethanol	**79.1**		mg/kg	± 10%	Internal Method - GC-FID	*EUSELI*

LP110: No pesticide residue detected (NMKL 195 mod.).

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Pia Waldefelt (p.w@sweoat.se)

Mariana Eriksson, ASM

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Test was performed by

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EUSELI	Eurofins Food & Feed Testing Sweden (Lidköping)
EUSELI2	Eurofins Environment Sweden, Lidköping

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AR-004 v27

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Performing laboratory if nothing else is stated: Eurofins Food & Feed Testing Sweden (Lidköping)

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AR-17-LW-064976-01

EUSELI-00177469

Client code:: LW1000416

Reference:
006-10511-134530

ANALYTICAL REPORT

Sample code:	**525-2017-11170028**
Client Sample:	40FO-131216
Received:	2017-11-17
Report finished:	2017-11-29
Client sample code	40FO-131216
Start of analysis	2017-11-17

		Analysis	Result	MRL	Unit	Uncert.	Method	Lab
SL403		Lead (Pb)	**< 0.040**		mg/kg	± 25%	NMKL No 161 1998 mod	*EUSELI2*
SL404		Cadmium (Cd)	**< 0.020**		mg/kg	± 25%	NMKL No 161 1998 mod	*EUSELI2*
J5012		Deoxynivalenol (Vomitoxin)	**<20**		µg/kg		Internal method	*EUHAWE3*
LP152	*	Ethanol	**54.9**		mg/kg	± 10%	Internal Method - GC-FID	*EUSELI*

LP110: No pesticide residue detected (NMKL 195 mod.).

Copy to:
Pia Waldefelt (p.w@sweoat.se)

Mariana Eriksson, ASM

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Test was performed by

EUHAWE3	Eurofins WEJ Contaminants GmbH (Hamburg)
EUSELI	Eurofins Food & Feed Testing Sweden (Lidköping)
EUSELI2	Eurofins Environment Sweden, Lidköping

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Uncert: Measurement uncertainty

AR-004 v27

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Performing laboratory if nothing else is stated: Eurofins Food & Feed Testing Sweden (Lidköping)

Rapport utfärdad av
ackrediterat laboratorium

Report Issued by
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AR-15-SB-064039-01

EUSEJO2-00168498

Client code:: LW1000416

Reference:
EOL 6960-109911

ANALYTICAL REPORT

Sample code:	**527-2015-11240612**
Client Sample:	PL40FG - FG40-210915
Received:	2015-11-24
Report finished:	2015-12-03
Start of analysis	2015-11-25 09:59
Client sample code	PL40FG - FG40-210915

	Analysis	Result Unit	Num	Method	Lab
UMF50	Aerobic Plate Count 30°C	< 3.0 log cfu/g	< 1000	3M 01/01-09/89	*EUSEJO2*
UMD53	Enterobacteriaceae 37°C	< 1.0 log cfu/g	< 10	NMKL 144	*EUSEJO2*
UMP73	Moulds	< 2.0 log cfu/g	< 100	NMKL 98	*EUSEJO2*
UMN88	Yeast	< 2.0 log cfu/g	< 100	NMKL 98	*EUSEJO2*
UMY2U *	Spore-forming Aerobe Mesophilic Count	< 1 cfu/g		Internal Method	*EUSEJO2*

Copy to:
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Katrin Peterson, ASM Telefon: +46 10 490 8352

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Test was performed by

EUSEJO2 Eurofins Food & Feed Testing Sweden (Jönköping)

The laboratory/laboratories are accredited by the respective national accreditation body. Non-accredited tests are marked *.

Symbol description: AR-002 MI v51
* Not accredited

Uncert: Measurement uncertainty

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Rapport utfärdad av
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AR-15-LW-056690-01

EUSELI-00112619

Client code:: LW1000416

Reference:
EOL 6960-109913

ANALYTICAL REPORT

Sample code:	**525-2015-11260185**
Client Sample:	PL40FG - FG40-210915
Received:	2015-11-26
Report finished:	2016-01-07
Client sample code	PL40FG - FG40-210915
Start of analysis	2015-11-26

	Analysis	Result	MRL	Unit	Uncert.	Method	Lab
LP04Z	Water (Karl Fischer)	0.81		g/100 g	± 25%	ISO 5536:2009	EUSELI
LP06V	Ash total	3.26		g/100 g	± 10%	NMKL 173	EUSELI
LP021	Crude Protein Kjeldahl (Nx6,25)	2.34		g/100 g	± 10%	NMKL 6	EUSELI
LP06X	Fat acc. SBR mod.	83.0		g/100 g	± 10%	SLV VF 1980	EUSELI
LP056	C 6:0 (Caproic acid)	<0.1		% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 8:0 (Caprylic acid)	<0.1		% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 10:0 (Capric acid)	<0.1		% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 12:0 (Lauric acid)	<0.1		% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 14:0 (Myristic acid)	0.2		% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 14:1 (Myristoleic acid)	<0.1		% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 15:0 (Pentadecanic acid)	<0.1		% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 15:1 n-5	<0.1		% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 16:0 (Palmitic acid)	16.9		% of fatty acids	± 10%	Internal Method - GC-FID	EUSELI
LP056	C 16:1 n-7 (Palmitoleic acid)	0.2		% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 17:0 (Margaric acid)	<0.1		% of fatty	± 20%	Internal Method -	EUSELI

The laboratory/laboratories are accredited by the respective national accreditation body. Non-accredited tests are marked *.

Symbol description:

AR-004 v25

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Performing laboratory if nothing else is stated: Eurofins Food & Feed Testing Sweden (Lidköping)

			acids		GC-FID	
LP056	C 17:1 n-7 (Heptadecenoic acid)	<0.1	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 18:0 (Stearic acid)	1.7	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 18:1 n-9 (Oleic acid)	37.7	% of fatty acids	± 10%	Internal Method - GC-FID	EUSELI
LP056	C 18:2 n-6 (Linoleic acid)	38.4	% of fatty acids	± 10%	Internal Method - GC-FID	EUSELI
LP056	C 18:3 n-3 (α-Linolenic acid)	1.3	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 18:3 n-6 (γ-Linolenic acid)	<0.1	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 18:4 n-3 (Octadecatetraenoic acid)	<0.1	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 20:0 (Arachidic acid)	0.1	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 20:1 n-9 (Gadoleic acid)	0.6	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 20:2 n-6 (Eicosadien acid)	<0.1	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 20:3 n-6	<0.1	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 20:3 n-3	<0.1	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 20:4 n-6 (Aracidonic acid)	<0.1	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 20:4 n-3	<0.1	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 20:5 n-3 (EPA)	<0.1	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 22:0 (Behenic acid)	<0.1	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 22:1	0.2	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 22:2 n-6 (Docosadienoic acid)	0.1	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 22:4 n-6	<0.1	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 22:5 n-6	<0.1	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 22:5 n-3 (Docosapentaenoic acid)	<0.1	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 22:6 n-3 (DHA)	<0.1	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	C 24:0 (Lignocerlc acid)	<0.1	% of fatty	± 20%	Internal Method -	EUSELI

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AR-004 v25

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Performing laboratory if nothing else is stated: Eurofins Food & Feed Testing Sweden (Lidköping)

			acids		GC-FID	
LP056	C 24:1 n-9 (Tetracosenoic acid)	<0.1	% of fatty acids	± 20%	Internal Method - GC-FID	EUSELI
LP056	Saturated fatty acids	19.2	% of fatty acids		Internal Method - GC-FID	EUSELI
LP056	Mono-unsaturated fatty acids total	38.7	% of fatty acids		Internal Method - GC-FID	EUSELI
LP056	Poly-unsaturated fatty acids total	39.9	% of fatty acids		Internal Method - GC-FID	EUSELI
LP056	Total Fatty Acids	97.7	% of fatty acids		Internal Method - GC-FID	EUSELI
LP056	Unidentified Compounds	2.3	% of fatty acids		Internal Method - GC-FID	EUSELI
LP056	Fatty Acids, Sum Of Omega 6 Calc.	38.5	% of fatty acids		Internal Method - GC-FID	EUSELI
LP056	Fatty Acids, Sum Of Omega 3 Calc.	1.3	% of fatty acids		Internal Method - GC-FID	EUSELI
LP056	Fatty Acids, Omega6/Omega3 Ratio	29.13			Internal Method - GC-FID	EUSELI
LW0U4 *	Saturated fatty acids (calculated)	16.23	g/100 g			EUSELI
LW0U4 *	Mono-unsaturated fatty acids total (calculated)	30.71	g/100 g			EUSELI
LW0U4 *	Poly-unsaturated fatty acids total (calculated)	31.66	g/100 g			EUSELI
LW0U4 *	Total Fatty Acids (calculated)	77.52	g/100 g			EUSELI
LW0U4 *	Unidentified Compounds (calculated)	1.83	g/100 g			EUSELI
LW0U4 *	Fatty Acids, Sum Of Omega 6 (calculated)	30.55	g/100 g			EUSELI
LW0U4 *	Fatty Acids, Sum Of Omega 3 (calculated)	1.03	g/100 g			EUSELI
LP00F	Glucose	<0.04	g/100 g	± 25%	AOAC 982.14, mod.	EUSELI
LP00D	Fructose	0.05	g/100 g	± 25%	AOAC 982.14, mod.	EUSELI
LP00Q	Sucrose	1.33	g/100 g	± 15%	AOAC 982.14, mod.	EUSELI
LP00J	Lactose	<0.04	g/100 g	± 25%	AOAC 982.14, mod.	EUSELI
LP00L	Maltose	<0.04	g/100 g	± 25%	AOAC 982.14, mod.	EUSELI
LW0U5 *	Total Sugar (calculated)	1.38	g/100 g			EUSELI
LP06Z	Carbohydrate (calculated)	10.6	g/100 g		(EU) No 1169/2011	EUSELI
SLC18	Sodium (Na)	< 100	mg/kg	± 20%	NMKL No 161 1998 mod	EUSELI2
SL403	Lead (Pb)	0.044	mg/kg	± 20%	NMKL No 161 1998 mod	EUSELI2
SL404	Cadmium (Cd)	< 0.010	mg/kg	± 20%	NMKL No 161 1998 mod	EUSELI2

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Symbol description:

AR-004 v25

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Performing laboratory if nothing else is stated: Eurofins Food & Feed Testing Sweden (Lidköping)

SL402	Arsenic (As)	< 0.050	mg/kg	± 35%	NMKL No 161 1998 mod	*EUSELI2*
SL399	Mercury (Hg)	< 0.020	mg/kg	± 30%	EN 16277:2012	*EUSELI2*
LP072	Energy value kJ (calculated)	3291	kJ/100 g		(EU) No 1169/2011	*EUSELI*
LP072	Energy value kcal (calculated)	787	kcal/100 g		(EU) No 1169/2011	*EUSELI*
LP130: No pesticide residue detected (NMKL 195 mod.).						

Copy to:
Pia Waldefelt (p.w@sweoat.se)

Per-Olov Södergren, ASM

This test report has been created electronically and has been verified and authorised.

Test was performed by

EUSELI Eurofins Food & Feed Testing Sweden (Lidköping)
EUSELI2 Eurofins Environment Sweden, Lidköping

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Performing laboratory if nothing else is stated: Eurofins Food & Feed Testing Sweden (Lidköping)

Rapport utfärdad av
ackrediterat laboratorium

Report issued by
Accredited Laboratory

Eurofins Food & Feed Testing Sweden (Lidköping)
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Swedish Oat Fiber
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AR-17-LW-026048-01

EUSELI-00160096

Client code:: LW1000416

Reference:
006-10511-125257

ANALYTICAL REPORT

Sample code:	**525-2017-05160090**
Client Sample:	PL40-20170426
Received:	2017-05-16
Report finished:	2017-06-02
Client sample code	PL40FG-20170426
Start of analysis	2017-05-16

		Analysis	Result	MRL	Unit	Uncert.	Method	Lab
SL402		Arsenic (As)	< 0.10		mg/kg	± 35%	NMKL No 161 1998 mod	*EUSELI2*
SL403		Lead (Pb)	< 0.040		mg/kg	± 20%	NMKL No 161 1998 mod	*EUSELI2*
SL404		Cadmium (Cd)	< 0.020		mg/kg	± 20%	NMKL No 161 1998 mod	*EUSELI2*
SL399		Mercury (Hg)	< 0.020		mg/kg	± 30%	EN 16277:2012	*EUSELI2*
LP152	*	Ethanol	30.4		mg/l	± 10%	Internal Method - GC-FID	*EUSELI*

LP110: No pesticide residue detected (NMKL 195 mod.).

Copy to:
Pia Waldefelt (p.w@sweoat.se)

Per-Olov Södergren, ASM

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Test was performed by

EUSELI	Eurofins Food & Feed Testing Sweden (Lidköping)
EUSELI2	Eurofins Environment Sweden, Lidköping

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Performing laboratory if nothing else is stated: Eurofins Food & Feed Testing Sweden (Lidköping)

AR-004 v26

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Report issued by
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AR-16-LW-028384-01

EUSELI-00128339

Client code:: LW1000416

Reference:
EOL 8556-112996

ANALYTICAL REPORT

Sample code:	525-2016-05250211
Client Sample:	PL40 FG - 100615
Received:	2016-05-25
Report finished:	2016-06-03
Client sample code	PL40 FG - 100615
Start of analysis	2016-05-25 08:00:12

	Analysis	Result	Unit	Uncert.	Method	Lab
LW0PB	Gluten	<7.0	mg/kg	± 40%	ELISA Ridascreen	*EUSELI*

Report comments:
The limit for gluten-free products is 20 mg/kg and products with very low level 100 mg/kg according to 2009/41/EG.
ELISA-method (gluten) with monoclonal antibody R5. Reacts with gliadins from wheat and corresponding prolamins from rye and barley.

Copy to:
Pia Waldefelt (p.w@sweoat.se)

Björn Sahlberg, ASM

This test report has been created electronically and has been verified and authorised.

Test was performed by

EUSELI Eurofins Food & Feed Testing Sweden (Lidköping)

The laboratory/laboratories are accredited by the respective national accreditation body. Non-accredited tests are marked *.

Symbol description:
* Not accredited

AR-003 v78
1.75 130516

Uncert: Measurement uncertainty

Measurement uncertainty, unless otherwise stated, are reported as expanded uncertainty with coverage factor 2. Exceptions related to analysis performed outside Sweden may occur. Additional information can be obtained upon request.

Rapport utfärdad av ackrediterat laboratorium

Report issued by Accredited Laboratory

Eurofins Food & Feed Testing Sweden (Lidköping)
Box 887
Sjöhagsg. 3
SE-53119 Lidköping
www.eurofins.se

Swedish Oat Fiber
Ellen Hedrén
Båtafjordsvägen 12
432 63 Bua

AR-16-LW-028385-01

EUSELI-00128339

Client code:: LW1000416

Reference:
EOL 8556-112996

ANALYTICAL REPORT

Sample code:	525-2016-05250212
Client Sample:	PL40 FG - 220915
Received:	2016-05-25
Report finished:	2016-06-03
Client sample code	PL40 FG - 220915
Start of analysis	2016-05-25 08:00:12

	Analysis	Result Unit	Uncert.	Method	Lab
LW0PB	Gluten	<7.0 mg/kg	± 40%	ELISA Ridascreen	*EUSELI*

Report comments:
The limit for gluten-free products is 20 mg/kg and products with very low level 100 mg/kg according to 2009/41/EG.
ELISA-method (gluten) with monoclonal antibody R5. Reacts with gliadins from wheat and corresponding prolamins from rye and barley.

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AR-003 v78
1.75 130516

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Stability Study Oat Oil PL40		week 0	week 4	week 8	week 9	week 12	week 14	week 20	month 6	month 9	month 12	month 15	month 18	month 21	month 24	month 30	month 35	month 42	
PL40-FG-300415 RT	PV meq/kg			2.8			1.3	0.8	1.04	3.16	8.1	11.1	14	14.1	17.8	32.32	41.2	50.6	AV = anisidine value, secondary oxidation
	FFA mg/g			9.9			n/a	8.9	0.39	4.83	9				9.6				
	emulsion mm (RT/4C)	3,1/6,5					2,8/6,0		2,7/6,0	2,6/5,5	2,4/6,8	2,9/6,3	2,2/5,0	2,8/4,6	2,5/5,0				
	H2O ppm	0.59%					0.40%		0.58%	0.66%	1.12%	1.40%	1.20%	1.27%	1.28%				
PL40-FG-300415 4C	PV meq/kg			2.8			0.9	0.6	0.38	2.01	5.3	10.7	14.6	16.9	22.4	30.35	37.9	38.3	
	FFA mg/g			9.8			n/a	8.6	0.21		9.1				8.9				
	emulsion mm (RT/4C)			2,2/6,0			2,5/6,0		2,7/6,5	2,6/5,5	1,9/6,4	3/6,0	2,1/4,6	2,8/5,1	2,5/4,2				
	H2O ppm			0.40%			0.40%		0.42%	0.59%	1.24%	1.70%	1.34%	1.27%	1.82%				
PL40-FG1-100615 RT	PV meq/kg		2	1.1		0.7			n/a	1.1	1.32	3.8	5.59	4.72	3.81	9.93	11.2	13.07	
	FFA mg/g		n/a	n/a		n/a	12.1		0.5	14.6	12.7				14				
	emulsion mm (RT/4C)	2,2/5,0	2/5,4	2,1/5,5		2,6/5,5			2,2/5,4	2,1/5,5	2/5,5	2,1/5,4	2,3/4,8	2,6/4,6	2,1/4,8				
	H2O ppm	15000 ppm	15700	1.60%		1.73%			1.75%	1.73%	1.74%	1.95%	1.95%	1.95%	1.70%				
PL40-FG1-100615 4C	PV meq/kg		1	1.4		0.3			n/a	0.58	0	2.53	3.37	1.41	1.01	4.41	4.5	4.81	
	FFA mg/g		n/a	n/a		n/a	10.9		0.95	15.1	12.7				12.3				
	emulsion mm (RT/4C)		2,2/5,2	2,1/5,5		2,6/5,7			2,2/5,4	1,9/5,2	2/5,6	2,1/5,3	1,9/4,6	2,7/5,0	2,0/5,4				
	H2O ppm		15700	1.60%		1.78%			1.57%	1.87%	2.13%	2.44%	2.50%	3.05%	2.80%				
40FO-260916 4C	PV meq/kg	0									5.22				18.84				
40FO-251016 4C	PV meq/kg	1.82									5.5				24.09				
40FO-0314-1 4C	PV meq/kg																	11.71	
40FO-131214 4C	PV meq/kg																35.58		
40FO-050515 4C	PV meq/kg															26.51			
40FO-130515 RT	PV meq/kg															58.64			
40FO-180515 RT	PV meq/kg															70.47			

Stability Study Oat Oil PL40		start	month 3	month 6	month 9	month 12	month 15	month 18	month 21	month 24
PL40FG 20170426 RT	PV meq/kg	0.3		3.17		8.63	11.85	14.51		
PL40FG 20170426 4C	PV meq/kg	0.3		1.37		2.61	4.82	7.66		

start H2O	PL	ins	FFA
2870ppm	44.80%	0.30%	

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Analytical Report Form

Title:
Lipid Class and Fatty Acid Analysis of Oil

Prepared for:
Oat Services Ltd.
226 Bassett Avenue
Southampton
Hampshire
SO16 7FU

Compiled by:
Nutrition Analytical Service
Institute of Aquaculture
University of Stirling
Stirling
FK9 4LA
Telephone +44(0)1786 467997

Contract number: 16-OAT-019

Date of report: 22-12-16

UNIVERSITY OF STIRLING

Analytical Report Form

Company name:	Oat Services Ltd	Date sample received:	19-12-16
Customer contact name:	Cark Maunsell	Date report prepared:	22-12-16
Contract number:	16-OAT-019	No. of samples:	4
P.O. number:	P2060	Sample type:	High fat oils

Analysis performed:	Lipid Class	Date of test: 20-12-16
	Fatty Acid Analysis	Date of test: 19-12-16
		Date of test:
		Date of test:
		Date of test:

Methods used:	LM002.R01 Lipid Class SOM
Report prepared by:	Dr M. Sprague

Sample condition (detail any non-conformance):_____

_____

Name of approver: Fiona Strachan Signature:

(Quality Manager)

Date: 22/12/16

RESULTS

LIPID CLASS COMPOSITION (% total lipid) OF OILS

LIPID CLASS	SAMPLE ID			
	5073 16/12/2016 PL40-FG 40FG-160516	5074 16/12/2016 PL40-FG 40FG-210915	5075 16/12/2016 PL40-FG 40FG-100615	5076 16/12/2016 PL15 15FO-250915
Wax/Sterol esters	<LOQ	<LOQ	<LOQ	<LOQ
Triacylglycerols	37.0	33.4	32.5	44.4
Free fatty acids	11.4	8.8	8.3	8.4
Cholesterol/sterols	9.5	7.7	7.7	11.8
Unknown neutral lipid¶	2.1	2.6	2.5	4.2
Total neutral lipids	**60.0**	**52.5**	**51.0**	**68.8**
Monogalactosyldiacylglycerols	2.4	3.0	3.5	2.4
Unknown glycolipid*	6.3	9.5	8.1	4.8
Ceramides	4.0	4.4	6.0	4.6
Digalactosyldiacylglycerols	7.2	8.2	8.6	4.9
Unknown polar lipid#	0.6	0.8	1.6	1.5
Phosphatidylethanolamine	2.9	3.9	4.0	2.6
Phosphatidic acid / Phosphatidylglycerol / cardiolipin	1.2	1.1	1.3	0.9
Phosphatidylinositol	3.6	4.6	4.1	0.8
Phosphatidylserine	0.8	1.1	0.7	1.9
Phosphatidylcholine	6.0	6.0	6.5	3.6
Sphingomyelin	<LOQ	<LOQ	<LOQ	<LOQ
Lysophosphatidylcholine	1.0	1.0	1.1	0.5
Pigmented material	4.0	3.9	3.5	2.7
Total polar lipids	**40.0**	**47.5**	**49.0**	**31.2**

Possibly Sulfolipid
*May contain traces of ceramides
¶ Possibly diacylglycerol
Above values calculated from analyses performed in duplicate, as determined by HPTLC

Fatty acid composition (% total fatty acids and mg FA.100g^{-1}) of total lipid from Oil

Fatty acid	5073 16/12/2016 PL40-FG 40FG-160516		5074 16/12/2016 PL40-FG 40FG-210915		5075 16/12/16 PL40-FG 40FG-100615		5076 16/12/2016 PL15 15FO-250915	
	%	mg. 100g^{-1}	%	mg. 100g^{-1}	%	mg. 100g^{-1}	%	mg. 100g^{-1}
14:0	0.22	192.00	0.21	186.00	0.18	152.00	<LOQ	<LOQ
15:0	0.10	86.00	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
16:0	17.31	15038.00	17.09	14813.00	16.97	14641.00	15.73	13933.00
18:0	1.90	1654.00	1.82	1580.00	1.68	1447.00	1.87	1660.00
20:0	0.13	115.00	0.15	127.00	0.11	95.00	0.15	130.00
22:0	0.10	88.00	0.11	94.00	0.12	107.00	0.07	64.00
24:0	0.11	92.00	0.11	97.00	0.11	98.00	0.10	88.00
Total saturated	**19.87**	**17265.00**	**19.49**	**16897.00**	**19.17**	**16540.00**	**17.93**	**15875.00**
16:1n-9	0.06	53.00	<LOQ	<LOQ	0.06	51.00	<LOQ	<LOQ
16:1n-7	0.24	207.00	0.20	171.00	0.26	221.00	0.23	200.00
18:1n-9	38.08	33081.00	37.30	32333.00	36.28	31302.00	41.27	36552.00
18:1n-7	0.94	817.00	0.92	801.00	0.94	807.00	0.85	750.00
20:1n-11	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
20:1n-9	0.65	561.00	0.64	556.00	0.64	548.00	0.73	645.00
20:1n-7	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
22:1n-11	0.06	53.00	<LOQ	<LOQ	0.06	49.00	<LOQ	<LOQ
22:1n-9	0.07	63.00	<LOQ	<LOQ	0.06	54.00	<LOQ	<LOQ
24:1n-9	0.08	72.00	0.06	56.00	0.07	57.00	0.08	70.00
Total monounsaturated	**40.18**	**34907.00**	**39.12**	**33917.00**	**38.35**	**33089.00**	**43.15**	**38217.00**
18:2n-6	38.72	33639.00	39.97	34654.00	40.99	35371.00	37.62	33318.00
18:3n-6	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
20:2n-6	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
20:3n-6	<LOQ	<LOQ	0.06	54.00	<LOQ	<LOQ	0.07	58.00
20:4n-6	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
22:4n-6	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
22:5n-6	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Total n-6 PUFA	**38.72**	**33639.00**	**40.04**	**34708.00**	**40.99**	**35371.00**	**37.69**	**33376.00**
18:3n-3	1.22	1063.00	1.35	1168.00	1.49	1285.00	1.24	1094.00
18:4n-3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
20:3n-3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
20:4n-3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
20:5n-3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
22:5n-3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
22:6n-3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Total n-3 PUFA	**1.22**	**1063.00**	**1.35**	**1168.00**	**1.49**	**1285.00**	**1.24**	**1094.00**
16:2	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
16:3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
16:4	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
	<LOQ	**<LOQ**	**<LOQ**	**<LOQ**	**<LOQ**	**<LOQ**	**<LOQ**	**<LOQ**
Total PUFA	**39.95**	**34702.00**	**41.38**	**35876.00**	**42.48**	**36656.00**	**38.92**	**34470.00**
Total	**100.00**	**86874.00**	**100.00**	**86690.00**	**100.00**	**86285.00**	**100.00**	**88562.00**

Limit of quantification (LOQ) for fatty acid analysis is 0.06%