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*Specializing in FDA Regulatory Matters*

05-19-07 PC? 59 RCVD

May 26, 2007

Office of Food Additive Safety (HFS-255)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

RE: Notification of GRAS Determination for Krill-based Lecithin in Food

Dear Sir/Madame:

In accordance with proposed 21 CFR § 170.36 (Notice of a claim for exemption based on a GRAS determination) published in the Federal Register (62 FR 18939-18964), I am submitting in triplicate, as the agent to the notifier, Enzymotec, a GRAS Notification for krill-based lecithin under the conditions of its intended use in food.

Please let me know if you have any questions.

Sincerely,

Edward A. Steele  
President

Enclosures



Specializing in FDA Regulatory Matters

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BY:.....

**I GRAS Exemption Claim**

**A. Claim of Exemption From the Requirement for Premarket Approval Pursuant to Proposed 21 CFR §170.36(c)(1) [62 FR 18938 (17 April 1997)]**

Krill-based lecithin has been determined to be Generally Recognized As Safe (GRAS), consistent with Section 201(s) of the *Federal Food, Drug, and Cosmetic Act*. This determination is based on scientific procedures as described in the following sections, under the conditions of its intended use in food. Therefore, the use of krill-based lecithin in food, as described below, is exempt from the requirement of premarket approval.

Signed,

\_\_\_\_\_  
Edward A. Steele

5/26/07  
\_\_\_\_\_  
Date

Agent for:

Enzymotec, Ltd  
P.O. Box 6, Migdal HaEmeq  
Israel 23106

**B. Name and Address of Notifier**

Ms. Iris Meiri-Bendek  
Regulatory Affairs Manager  
Enzymotec, Ltd  
P.O. Box 6, Migdal HaEmeq  
Israel 23106

**C. Common Name of the Notified Substance**

The substance is commonly known as lecithin. Commercial lecithin is a complex mixture obtained from edible food sources that is characterized by the principle component phosphatidyl choline. The composition of both the phosphatidyl choline and the lecithin mixture may vary depending on the source from which it is obtained, as described below. Because the fatty acid composition of marine-derived substances differs from that of plants in a way significant for nutrition, a unique name is appropriate. In this notice, we are describing the product as krill-based lecithin although we have described it in previous correspondence as marine-derived phosphatidyl choline, or MD-PC.

**D. Conditions of Intended Use in Food**

The lecithin derived from krill is intended for use as a nutrient in those foods, at levels listed below in Table I, that do not contain other significant sources of docosahexaenoic acid (DHA) or eicosapentaenoic acid (EPA) as ingredients.

**Table I**

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Food	% Krill-based Lecithin
Breakfast bars	3.8
Dairy product analogs (soy products)	0.6
Fat spreads	10.0
Milk-based beverages	0.6
Yogurt	0.7
Soft candy	3.3

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**E. Basis for the GRAS Determination**

Pursuant to 21 CFR § 170.30, krill-based lecithin has been determined to be GRAS on the basis of scientific procedures.

**F. Availability of Information**

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

Ms. Iris Meiri-Bendek  
Regulatory Affairs Manager  
Enzymotec, Ltd  
P.O. Box 6, Migdal HaEmeq  
Israel 23106

Should the U.S. Food and Drug Administration (FDA) have any questions or additional information requests regarding this notification, Enzymotec, Ltd. will supply these data and information.

## II. Detailed Information About the Identity of the Substance

### A. Identity

#### Chemical or common names

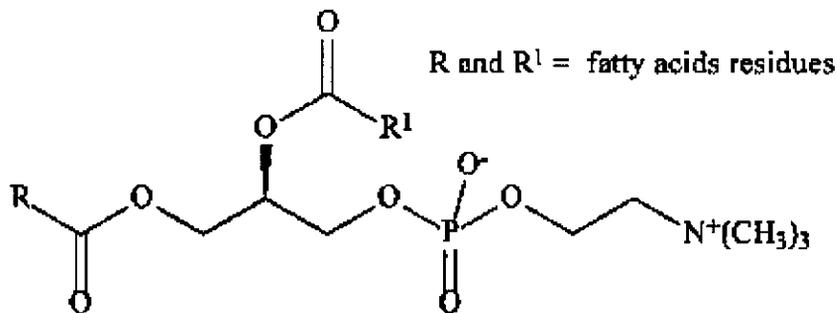
Phosphatidylcholine

1, 2-diacyl-*sn*-glycero-3-phosphocholine

Lecithin

#### Structure of Phosphatidylcholine

Phosphatidylcholine is a phospholipid that is a major constituent of cell membranes. More than 90% of bile phospholipids are represented by phosphatidylcholine. Phosphatidylcholine is also known as, PtdCho and lecithin. It is represented by the chemical structure in Figure 1:



**Figure 1. Phosphatidylcholine**

The term lecithin itself has different meanings when used in chemistry and biochemistry than when used commercially. Chemically, lecithin is phosphatidylcholine. Commercially, the term lecithin refers to a natural mixture of neutral and polar lipids containing a large fraction of

phosphatidylcholine. Lecithin is naturally consumed through a diet containing lecithin rich foods such as egg yolk, soybeans, grains, wheat germ, fish, legumes, yeast, and peanuts, to name a few examples.

Phosphatidylcholine, which is a relatively polar lipid, is present in commercial lecithin at concentrations ranging from 20 to 90%. Soybean, sunflower and rapeseed are the major plant sources of commercial lecithin with soybeans as the most common source. Plant lecithins are GRAS (generally recognized as safe) for use in food with no limitation other than current good manufacturing practice (21 CFR 184.1400). The fatty acid substituents on R and R<sup>1</sup> positions of phosphatidylcholine from plant and animal sources differ. The R<sup>1</sup> second or middle carbon of the phospholipid molecule is mainly occupied by unsaturated fatty acids.

Lecithin from krill is produced in two grades, A & B, differing in the purification level of the phosphatidylcholine. In lecithin derived from krill, the combined DHA (docosahexaenoic acid) and EPA (eicosapentaenoic acid) content is approximately 14-18% for Grade A and 20-25% for Grade B.

Attached in Appendix A is a comparison of the Enzymotec krill-based lecithin products for both Grades A and B to the phospholipid content of commercial soy lecithin (Table A-1) and a comparison of the fatty acid content of commercial lecithin and menhaden oil to Grades A and B (Table A-2). As the comparison of soy- and krill-based lecithin products shows, the overall compositions are essentially the same except for the fatty acids, which reflect the different sources. The phospholipid composition shown in Table A-1 is very similar for the other two sources of lecithin. The fatty acid composition of Grades A and B is similar to that of menhaden oil and differs from soybean lecithin fatty acid composition in having notable amounts of the omega-3 fatty acids, particularly EPA and DHA, as expected.

## Product Specifications

**Table II – Krill-based lecithin specifications**

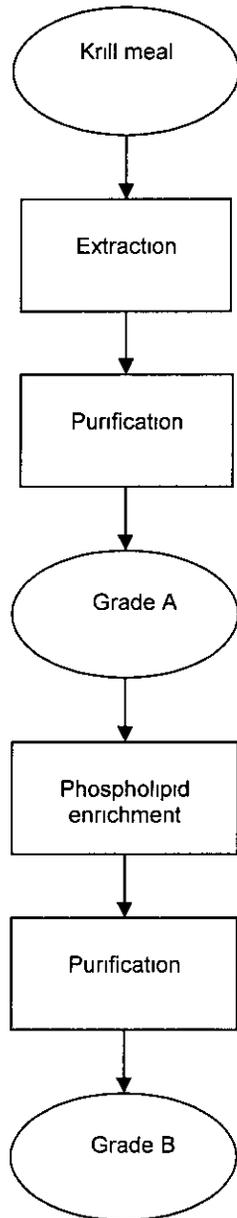
<b>Parameter</b>	<b>Grade A Specification</b>	<b>Grade B Specification</b>
Total phospholipids (%w/w)	40-50	70-95
PV (meq/Kg)	<5.0	<5.0
Moisture (%)	<3.0	<3.0
Lead, cadmium, mercury	<1ppm	<1ppm

## **B. Method of Manufacture and Compositional Analysis**

The source for this lecithin will be krill, which are tiny, free-swimming, shrimp-like crustaceans (euphausiids), which exist in large numbers in the open sea, mainly near Antarctica. The raw material to be extracted, krill meal, is a biomass composed of lipids, sugars and proteins. By using a solvent extraction process, the proteins and free sugars are removed so that only lipids are left. Various solvents may be used for the extraction process, all of which are of food-grade quality and are used and removed from the product in accordance with current good manufacturing practice. The resulting extract, Krill-based lecithin Grade A may be further processed to enrich the phospholipid fraction and obtain Grade B (see Figure 2). Food grade antioxidants are added to the products in accordance with good manufacturing practice.

Table B-1 contains compositional data of several batches per each grade. Grade A includes phospholipids, neutral lipids and other lipids (e.g. glycolipids), while Grade B includes almost exclusively phospholipids, almost no neutral lipids and about 8-10% of "other" lipids. The "Other lipids" were calculated through subtraction of the total phospholipids and total neutral lipids from the total lipids. As indicated by the toluene and hexane insoluble analyses, the product does not include protein or free sugars. Table B-2 provides the main fatty acid composition for total product Grades A and B, as % fatty acids of the product (by mass) and the fatty acid composition of the phospholipids and the phosphatidylcholine.

**Figure 2. Krill-based lecithin–Manufacturing Process Diagram**



### **C. Intended use**

Krill-based lecithin is intended for addition to a limited number of conventional foods as a nutritional ingredient. It is intended for the general population at the levels identified in Table I to dairy products (milk drinks and yogurt types), soy products, spreads, breakfast bars, and soft candy. We recognize that there are Standard of Identity requirements for some of these proposed foods and do not intend to refer to them by the commonly recognized names such as milk, chocolate or yogurt.

### **D. Levels of Addition**

The maximum levels of addition as shown in Table I are calculated so as not to exceed the upper limit of 3 g/day of DHA and EPA as outlined in the menhaden oil regulation. Use is limited to food groups already described in 21 CFR 184.1472 (with breakfast bars considered as a cereal substitute) where no other significant source of DHA or EPA is added. Thus, krill-based lecithin will not add any DHA or EPA to food above that which is already permitted.

### **E. Safety Assessment of Lecithin from Krill**

It is well established and recognized that phosphatidylcholine (lecithin) from either plant or animal sources is handled the same metabolically. Lecithin is absorbed into the mucosal cells of the small intestine, mainly in the duodenum and upper jejunum, following digestion by the pancreatic enzyme phospholipase A<sub>2</sub> (Arnesjo *et al.*, 1969; Belleville and Clement, 1969), by which the fatty acids in the 2 position are hydrolyzed to form lysophosphatidylcholine (lysolecithin) (Nieuwenhuizen *et al.*, 1974). Following absorption by the enterocytes, reacylation of lysolecithin takes place in these intestinal mucosal cells, reforming phosphatidylcholine, while the previously released fatty acids can be further used for triglyceride synthesis (Tso and Fujimoto, 1994). Phosphatidylcholine is then transported by the lymphatic system in the form of chylomicrons to the blood and metabolized by peripheral tissues. After the liver takes up the chylomicron remnants, the lipids are repackaged and secreted in the very low density lipoproteins (VLDL) (Ginsberg, 1998; Kang and Davis, 2000). Phosphatidylcholine is also incorporated into cell membranes, particularly in the lung. Phosphatidylcholine is also metabolized to choline, fatty acids and glycerol. The fatty acids and glycerol are either oxidized to produce energy or become involved in lipogenesis. Choline serves as a precursor of the neurotransmitter acetylcholine and serum choline levels have been shown to peak between 2 to 6 hours after oral intake of phosphatidylcholine.

One possible basis for the biological actions of phosphatidylcholine administered orally is that the fatty acid from the 2 position is being utilized for either (a) triglyceride synthesis during the course of lipid absorption in the small intestinal epithelial cells; (b) for the formation of phosphatidylcholine for membranes in the small intestinal epithelial cells; or (c) used by other organs in the body. The fatty acids of phosphatidylcholine are shuffled to suit the needs of the cell as they change over time, or as the phosphatidylcholine "parent molecule" is transported from tissue to tissue, cell to cell, or perhaps even from spot to spot within a membrane. Enzymes (hydrolases, acyltransferases) that remove or replace (re-esterify) fatty acids at position 2 of phosphatidylcholine are found in the intestinal epithelial cells, the hepatocytes, and other cells of the body. Phosphatidylcholine is also produced endogenously; for example, the liver secretes between 15–20 grams of phospholipids into the intestinal lumen and, of that, over 90% is phosphatidylcholine (Tso *et al*, 1977).

In summary, there is no reason to believe, given the metabolic sequelae described above, that the marine-derived phosphatidylcholine and associated lipids normally present in marine organisms would pose any different health hazards than plant oil-derived lecithins and lipids except, possibly, for differences in lipid content based on the marine origin or possible contaminants from such a source. The following will discuss the consequences of increased consumption of DHA and EPA resulting from krill-based lecithin, and the possible presence of source-based contaminants.

Recognizing that FDA has supplied tables of concentrations of menhaden oil in various foods consistent with safe levels of DHA and EPA, comparison of EPA + DHA concentrations in those foods from menhaden oil and krill-based lecithin may be done directly. In doing so, we are using FDA's statement in the response letter to GRN 000109 that menhaden oil contains 8% DHA and 14% EPA. Enzymotec concludes that the addition of krill-based lecithin to a small group of foods, other than baby foods, is GRAS at a level of approximately 1.5 gram per serving, which translates into a concentration that can be compared to that of menhaden oil, as described in the menhaden oil regulation. These levels are displayed in Table III. Because Enzymotec's lecithin is produced in two grades, and because Grade B has a higher concentration of DHA and EPA, we will use Grade B as an upper limit scenario. The average composition of DHA and EPA in Grade B lecithin is 7.5% and 14.7 %, respectively. Coincidentally, this total of 22.2 % is essentially the same as that given by FDA (22%) for menhaden oil. Thus, we will compare concentrations of krill-based lecithin in foods with that of menhaden oil (see Table III). Grade A is approximately 16% DHA + EPA so that will produce less DHA and EPA in the diet when added at 1.5 g/serving. Serving sizes are taken from reference amounts in 21 CFR 101.12.

**Table III****Concentrations of Krill-based Lecithin and Menhaden Oil as stated in 21 CFR 184.1472**

<b>Food</b>	<b>Reference amount (21 CFR 101.12)</b>	<b>% Krill-based lecithin</b>	<b>% Menhaden Oil</b>
Breakfast bars	40 g	3.8	
Dairy product analogs (soy products)	Not listed; milk-based drinks = 240 g	0.6	5.0
Fat spreads	15 ml; ~15 g	10.0	Fats and oils 12.0
Milk-based beverages	240 g	0.6	Milk products 5.0
Yogurt	225 g	0.7	Milk Products 5.0
Soft candy	45 g	3.3	4.0

The menhaden oil rule permits several additional applications where krill-based lecithin would not be used. The important point is that in all applications where either lecithin or menhaden oil might be used, the levels of lecithin (and subsequent levels of DHA+EPA) are lower than what is allowed from menhaden oil, sometimes much less. We agree with the limitation that krill-based lecithin not be used with other ingredients that are good sources of DHA or EPA; thus it will not be added to foods containing other significant sources of DHA or EPA as ingredients. The one food category discussed for krill-based lecithin that is not the subject of the menhaden oil rule is breakfast bars. However, these would generally substitute for cereals, which are allowed by the menhaden oil rule. According to 21 CFR 101.12, reference amounts for cereals range from 15 – 55 g. At a concentration of menhaden oil of 4.0%, this would range from 0.6 to 2.2 g menhaden oil. Therefore, the use of krill-based lecithin in breakfast bars would simply substitute for breakfast cereals at a level lower than that allowed for menhaden oil. We also note that dairy product analogs (soy products) can come in a variety of forms such as “soy milk” or yogurt substitute. The important thing is that these would replace milk-based products already permitted in 184.1472.

In sum, the use of krill-based lecithin in foods, as intended by Enzymotec, would contribute far less DHA + EPA than what is currently authorized from use of menhaden oil in these foods, as Krill-based lecithin GRAS notification

listed in 184.1472, or other fish oils subject to GRAS notifications. Importantly, it does not contribute to any increase in cumulative DHA + EPA intake because krill-based lecithin would simply provide equal or less of these fatty acids than that which has already been considered for these foods and concluded to be safe. While use may broaden the range of products with these fatty acids from which a consumer may choose, such products would simply provide alternative products to those that are currently permitted and would not add to the current cumulative intake for users of such products.

A second consideration is whether contaminants that might be stored in marine lipids could pose a risk to health. Krill have been a significant food for higher marine species and have presented no safety concern. Importantly, krill are very low on the food chain and would not bioaccumulate lipid-soluble contaminants as occurs in larger species. Nevertheless, because this ingredient is from the lipid fraction, we have conducted analyses for likely contaminants on two batches as found in Table C-1 in Appendix C. Because Grade B is made from Grade A, a simple calculation was performed using the exaggerated assumption that all of each contaminant would stay with the lecithin throughout the purification step and, thus, be concentrated by 2.5 times in the Grade B as compared to Grade A. This, of course, is unlikely but provides an upper-bound estimate. As seen, the levels are low and consistent with levels in other food ingredients.

Finally, krill, being a crustacean, could contain protein that might be allergenic to individuals allergic to certain crustaceans. However, the processing of the lipid fraction should reduce proteins to a negligible level. Nevertheless, based on the requirements of the Food Allergen Labeling and Consumer Protection Act of 2004, the word “krill” will appear in the ingredient list unless it can be shown that no protein is present; a successful notification is filed demonstrating no allergenic protein; or a successful petition is filed demonstrating that the ingredient does not cause an allergic response that could pose a risk to human health.

### **III. CONCLUSIONS**

In sum, based on the information provided above and the fact that the constituents of krill-based lecithin are commonly found in food, and because these lipids and phospholipids are essentially the same, and will be handled metabolically the same as those derived from plants, we conclude that scientific experts, generally, would recognize them to be as safe and as acceptable as plant lecithin and lipids. Further, we believe that there are no significant questions regarding the safety of krill-based lecithin that would appear to require additional safety studies, due to the prior consideration and acceptability by the Agency for plant-derived lecithin and other phospholipids and fish oil-derived omega-3 fatty acids.

## References

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Kang S and Davis RA. (2000) Cholesterol and hepatic lipoprotein assembly and secretion. *Biochim Biophys Acta.* 1529(1-3):223-230.

NAS IOM (National Academy of Sciences, Institute of Medicine) (1998) *Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline.* National Academies of Science Press, Washington, D.C.

Nieuwenhuizen W, Kunze H, de Haas GH (1974) Phospholipase A2 (phosphatide acylhydrolase, EC 3.1.1.4) from porcine pancreas. *Methods Enzymol.* 32(Part B):147-154.

Tso P, Balint JA, Simmonds WJ (1977) Role of biliary lecithin in lymphatic transport of fat. *Gastroenterology.* 73(6):1362-1367.

Tso P and Fujimoto K. (1991) The absorption and transport of lipids by the small intestine. *Brain Res Bull.* 27(3-4):477-482.

**Appendix A:**

**Typical phospholipid and fatty acid compositions of various lecithins**

**Table A-1- Phospholipid composition**

<b>Phospholipids Composition (%w/w)</b>	<b>Commercial fluid soy lecithin</b>	<b>Commercial High Grade Soy Lecithin</b>	<b>Grade A Krill- based Lecithin</b>	<b>Grade B Krill- based Lecithin</b>
Total	44	88	46	75-95
Phosphatidylcholine	35	78	36	60-85
Phosphatidylethanolamine	3	4	3	0-7
Phosphatidylinositol	1	0.5	2	1-5
Lysophosphatidylcholine	3	2.5	2	3-9
Others	2	3	3	1-6

**Table A-2 - Fatty acid composition**

<b>Fatty Acid Composition as % w/w of product</b>	<b>Soybean Lecithin*</b>	<b>Menhaden Oil*</b>	<b>Grade A** Krill-based Lecithin</b>	<b>Grade B** Krill-based Lecithin</b>
<b>22:6n3 (DHA)</b>	0.00	8.56	5.3	7.5
22:5n3	0.00	4.92		
22:1	0.00	0.35		
<b>20:5n3 (EPA)</b>	0.00	13.17	10.3	14.7
20:4	0.00	1.17		
20:1	0.00	1.33		
C18:4	0.00	2.74	0.9	0.8
C18:3	5.14	1.49		
C18:2	40.18	2.15	1.5	2.3
C18:1	10.57	14.53	13.2	5.8
C18:0	2.92	3.78	0.9	0.7
C16:1	0.40	10.48	5.2	1.2
C16:0	11.98	15.15	15.1	13.0
C14:0	0.10	7.96	7.1	1.2

\* Source - The USDA National Nutrient Database for Standard Reference

\*\* Average fatty acid composition of main fatty acids

**Appendix B: Krill-based Lecithin – Batch data**

**Table B-1 – Product composition**

		Grade A			Grade B		
		Batch	Batch	Batch	Batch	Batch	Batch
<b>Lipid composition</b>							
<b>Phospholipids (%w/w)</b>	Total	44.2	45.4	47.3	91.8	75.6	89.2
	Phosphatidyl choline (PC)	36.8	37.3	33.7	82.5	60.2	65.1
	Phosphatidyl ethanolamine (PE)	1.5	2.1	4.2	0.0	2.1	6.8
	Phosphatidylinositol (PI)	0.8	1.4	2.1	1.9	1.9	4.1
	Lysophosphatidyl choline (LPC)	2.8	2.8	1.1	6.4	8.1	3.3
	Others	2.3	1.9	6.3	1.1	3.4	5.3
	<b>Neutral lipids (%w/w)</b>	Total	52.0	50.0	47.3		
Diglycerides		19.8	13.0	13.6	ND		ND
Monoglycerides		2.0	4.9	2.2	ND		ND
Triglycerides		25.3	25.3	25.6	ND		ND
Free fatty acids		2.9	3.8	3.2	ND		0.8
Free cholesterol		ND	1	1.4	ND		ND
Cholesterol esters		2.0	2.1	1.4	ND		ND
<b>Other lipids (e.g. glycolipids) (%w/w) *</b>		3.8	4.5	5.3	8.0		10.0
<b>Toluene insoluble</b>		None	None	None			
<b>Hexane insoluble</b>		None	None	None			

\* calculated based on mass balance

Appendix B continued: Krill Lecithin – batch data

Table B-2 – fatty acid profile

	Grade A			Grade B		
	Batch [REDACTED]	Batch [REDACTED]	Batch 162-29A	Batch [REDACTED]	Batch [REDACTED]	Batch [REDACTED]
<b>Fatty acid profile (main fatty acids)</b>						
<u>As %w/w of the product</u>						
DHA	5.2	4.9	5.8	6.7	6.5	9.2
EPA	10.7	9.7	10.4	15.4	13.6	15.2
C18:4 n3	1.2	0.8	0.6	1.0	0.7	0.7
C18:2	1.1	1.3	2.2	2.5	1.1	3.3
C18:1	12.9	13.5	13.1	3.4	5.9	8.0
C18:0	0.8	0.9	0.9	0.5	0.8	0.8
C16:1	5.3	5.5	4.8	1.1	1.3	1.1
C16:0	14.4	16.1	14.7	13.2	12.0	13.8
C14:0	6.8	8.2	6.3	1.2	1.4	1.1
<u>As % of total fatty acids on Phospholipids</u>						
DHA	14.0	14.7	15.8	13.3	11.2	12.2
EPA	28.5	25.9	26.4	30.5	25.4	23.0
C18:4 n3	1.8	1.4	1.3	2.0	1.4	1.4
C18:2	6.0	5.7	5.7	5.8	2.2	6.2
C18:1	7.0	13.5	14.1	6.7	12.2	14.8
C18:0	1.3	1.3	1.5	1.0	1.3	1.5
C16:1	2.5	1.7	1.6	2.1	2.2	1.9
C16:0	25.0	22.8	22.5	26.0	26.2	25.6
C14:0	2.2	1.5	1.5	2.2	2.3	1.9

	Grade A			Grade B		
	Batch	Batch	Batch	Batch	Batch	Batch
<u>As % of total fatty acids on PC</u>						
DHA	13.2	11.7	13.5	12.5	12.0	13.7
EPA	31.6	27.9	32.1	30.6	27.7	31.2
C18:4 n3	1.7	1.6	0.3	1.9	1.5	0.3
C18:2	5.3	2.9	1.1	5.2	2.2	1.3
C18:1	6.8	13.0	13.5	6.8	11.3	12.9
C18:0	1.0	1.3	1.0	1.0	1.1	1.2
C16:1	2.0	1.9	1.8	2.1	2.3	1.7
C16:0	24.0	23.0	22.9	25.0	25.6	22.2
C14:0	1.7	1.0	1.5	1.9	2.4	1.2

## Appendix C: Chemical contaminants

Table C-1

	Grade A		Grade B (calculated values*)	
	Batch	Batch	Batch	Batch
PCBs – Total	8.5 ppb	2.1 ppb	≤21.3 ppb	≤5.4 ppb
PCBs –sum of 28,52,101,118,138,153,180	1.5 ppb	0.3 ppb	≤3.7 ppb	≤0.7 ppb
Dioxins and Furans WHO TEQ with DLs	1.6 ppt	0.5 ppt	≤3.9 ppt	≤1.3 ppt
Pesticides	Non detected	Non detected		
<u>Heavy metals</u>				
Total Arsenic	3.6 ppm	3.6 ppm	≤9.0 ppm	≤9.0 ppm
Inorganic Arsenic	<0.005ppm	Not measured	<0.0125 ppm	
Lead	<0.05 ppm	<0.05 ppm	<0.125 ppm	<0.125 ppm
Mercury	<0.005ppm	0.009ppm	<0.0125 ppm	≤0.0225 ppm
Cadmium	<0.05 ppm	<0.05 ppm	<0.125 ppm	<0.125 ppm

\* Grade B is a 2.5 fold concentrate of Grade A, thus the worse case scenario for contaminants would be that all of them are carried over to Grade B and therefore the levels in Grade A would be multiplied by 2.5.

Batch XXXXXXXXXX - Dioxins and Furans



**WELLINGTON**  
LABORATORIES

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2006-461-ENZ				
Table A: Dioxins and Furans. Oil (ppt)				
	Lab Blank	# of pks	80-63	# of pks
<b>Furans</b>				
2378-TCDF	ND (0.1)		4.3	
Total TCDFs	ND (0.1)		34.4	12
12378-PeCDF	ND (0.1)		0.8	
23478-PeCDF	ND (0.1)		1.1	
Total PeCDFs	ND (0.1)		8.8	6
123478-HxCDF	ND (0.1)		0.9	
123678-HxCDF	ND (0.1)		NDR (0.6)	
234678-HxCDF	ND (0.1)		0.7	
123789-HxCDF	ND (0.1)		NDR (0.3)	
Total HxCDFs	ND (0.1)		3.5	4
1234678-HpCDF	0.2		1.1	
1234789-HpCDF	ND (0.1)		NDR (0.3)	
Total HpCDFs	0.2	1	2.2	2
OCDF	0.3	1	NDR (1.6)	1
<b>Dioxins</b>				
2378-TCDD	ND (0.1)		ND (0.1)	
Total TCDDs	ND (0.1)		ND (0.1)	
12378-PeCDD	ND (0.1)		ND (0.1)	
Total PeCDDs	ND (0.1)		ND (0.1)	
123478-HxCDD	ND (0.1)		ND (0.1)	
123678-HxCDD	ND (0.1)		0.3	
123789-HxCDD	ND (0.1)		ND (0.1)	
Total HxCDDs	ND (0.1)		0.3	1
1234678-HpCDD	0.3		NDR (2.2)	
Total HpCDDs	0.3	1	1.5	1
OCDD	1.2	1	12.8	1
WHO TEQ (with DLs)	0.341 ppt		1.56 ppt	
September 20, 2006				
	Analyst		Date	



Batch [REDACTED] - PCBs

2006-461-ENZ Table B: PCB Levels in Oil Sample (ppt)		
	Lab Blank	80-63
<b>PCB CONGENERS</b>		
PCB #1 (mono)	15.1	69.0
PCB #3 (mono)	7.0	21.0
PCB #4/PCB #10 (di)	ND (139)	ND (90.0)
PCB #8 (di)	ND (110)	ND (70.9)
PCB #15 (di)	ND (119)	ND (76.7)
PCB #19 (tri)	ND (17.1)	ND (3.3)
PCB #18 (tri)	NDR (30.2)	128
PCB #16 (tri)	ND (18.9)	NDR (3.5)
PCB #28 (tri)	ND (6.5)	471
PCB #33 (tri)	ND (6.8)	319
PCB #22 (tri)	ND (6.6)	186
PCB #37 (tri)	ND (8.3)	150
PCB #54 (tetra)	ND (7.5)	ND (1.3)
PCB #52 (tetra)	ND (9.5)	343
PCB #49 (tetra)	ND (9.6)	139
PCB #44 (tetra)	ND (11.0)	144
PCB #64 (tetra)	ND (7.2)	114
PCB #74 (tetra)	ND (4.7)	103
PCB #70 (tetra)	ND (4.3)	209
PCB #66 (tetra)	ND (4.4)	144
PCB #66 (tetra)	ND (3.4)	98.6
PCB #81 (tetra)	ND (2.4)	ND (1.2)
PCB #77 (tetra)	ND (3.0)	24.0
PCB #104 (penta)	ND (14.1)	ND (2.4)
PCB #96 (penta)	ND (17.5)	ND (3.0)
PCB #95 (penta)	ND (5.7)	209
PCB #101 (penta)	ND (6.8)	238
PCB #99 (penta)	ND (4.6)	105
PCB #119 (penta)	ND (3.8)	11.2
PCB #87 (penta)	ND (5.4)	57.0
PCB #110 (penta)	ND (4.2)	132
PCB #123 (penta)	ND (2.9)	8.4
PCB #118 (penta)	13.5	109
PCB #114 (penta)	ND (11.5)	ND (2.7)
PCB #105 (penta)	ND (12.9)	83.0
PCB #126 (penta)	ND (2.7)	NDR (20.1)
PCB #155 (hexa)	ND (6.2)	ND (2.3)
PCB #151 (hexa)	ND (10.7)	47.0
PCB #149 (hexa)	ND (9.6)	133
PCB #153 (hexa)	NDR (51.1)	140
PCB #168 (hexa)	ND (9.9)	NDR (32.3)
PCB #138 (hexa)	ND (7.3)	129
PCB #158 (hexa)	ND (5.8)	ND (1.4)
PCB #128/167 (hexa)	ND (4.8)	28.7
PCB #156 (hexa)	ND (5.4)	NDR (29.2)
PCB #157 (hexa)	ND (5.5)	NDR (36.2)
PCB #189 (hexa)	ND (6.5)	ND (14.1)
PCB #188 (hepta)	ND (5.3)	ND (1.7)
PCB #179 (hepta)	ND (5.6)	10.6
PCB #178 (hepta)	ND (7.7)	ND (2.5)
PCB #187 (hepta)	ND (6.9)	28.8
PCB #183 (hepta)	ND (6.8)	16.2
PCB #174 (hepta)	ND (10.5)	35.5
PCB #177 (hepta)	ND (10.4)	NDR (26.2)
PCB #171 (hepta)	ND (9.9)	ND (8.5)
PCB #180 (hepta)	ND (37.2)	58.4
PCB #191 (hepta)	ND (7.2)	NDR (3.5)
PCB #170 (hepta)	ND (7.6)	ND (9.1)
PCB #189 (hepta)	ND (3.6)	4.7
PCB #202 (octa)	ND (4.5)	ND (26.1)
PCB #201 (octa)	ND (4.9)	ND (28.7)
PCB #200 (octa)	ND (5.1)	ND (30.2)
PCB #199 (octa)	ND (7.7)	ND (45.2)
PCB #203 (octa)	ND (6.7)	ND (39.2)
PCB #195 (octa)	ND (5.6)	ND (32.7)
PCB #194 (octa)	ND (5.7)	ND (33.2)
PCB #205 (octa)	ND (4.4)	ND (25.6)
PCB #208 (nona)	ND (5.1)	ND (12.6)
PCB #206 (nona)	ND (7.5)	ND (18.7)
PCB #209 (deca)	ND (6.8)	ND (16.7)
PCB #88 (penta)	ND (5.7)	ND (2.1)



Batch 80-63A – Pesticides



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2006-461-ENZ		
Table C : Organochlorine Pesticides in Oil (ng/g or PPB)		
	Lab Blank	80-63
<b>ORGANOCHLORINE</b>		
a-BHC	ND(3)	ND(4)
HXCB	ND(2)	ND(2)
b-BHC	ND(5)	ND(6)
g-BHC (LINDANE)	ND(3)	ND(4)
d-BHC	ND(4)	ND(5)
HEPTACHLOR	ND(3)	ND(3)
OXYCHLORDANE	ND(3)	ND(3)
HEPTACHLOR EPOXIDE	ND(3)	ND(4)
o,p' DDE	ND(4)	ND(5)
g-CHLORDANE	ND(3)	ND(4)
a-CHLORDANE	ND(3)	ND(3)
t-NONACHLOR	ND(3)	ND(4)
p,p' DDE	ND(3)	ND(4)
o,p' DDD	ND(5)	ND(7)
p,p' DDD	ND(5)	ND(7)
o,p' DDT	ND(4)	ND(5)
c-NONACHLOR	ND(3)	ND(4)
p,p' DDT	ND(4)	ND(5)
MIREX	ND(3)	ND(4)
ND - none detected (detection limits in brackets)		
		October 3, 2006
	Analyst	Date





Batch [REDACTED] - PCBs

2006-543-ENZ Table B: PCB Levels in Oil Sample (ppt)		
	Lab Blank	162-29D
<b>PCB CONGENERS</b>		
PCB #1 (mono)	4.5	45.4
PCB #3 (mono)	ND (5.7)	42.3
PCB#4/PCB#10 (di)	ND (174)	ND (20.8)
PCB #8 (di)	ND (156)	ND (18.6)
PCB #15 (di)	ND (176)	ND (21.0)
PCB #19 (tri)	ND (7.6)	ND (1.5)
PCB #18 (tri)	ND (8.3)	84.7
PCB #16 (tri)	ND (9.4)	71.8
PCB #28 (tri)	ND (6.0)	95.1
PCB #33 (tri)	ND (5.8)	55.1
PCB #22 (tri)	ND (5.8)	28.8
PCB #37 (tri)	ND (8.0)	18.1
PCB #54 (tetra)	ND (4.0)	ND (1.0)
PCB #52 (tetra)	ND (7.1)	55.6
PCB #49 (tetra)	ND (7.4)	39.4
PCB #44 (tetra)	ND (8.2)	34.4
PCB #54 (tetra)	ND (5.7)	24.9
PCB #74 (tetra)	ND (4.2)	18.0
PCB #70 (tetra)	ND (3.9)	39.3
PCB #66 (tetra)	ND (3.8)	26.4
PCB #56 (tetra)	ND (3.0)	19.5
PCB #81 (tetra)	ND (2.2)	ND (1.0)
PCB #77 (tetra)	ND (2.7)	5.1
PCB #104 (penta)	ND (8.2)	ND (2.0)
PCB #96 (penta)	ND (11.2)	ND (2.7)
PCB #95 (penta)	ND (3.8)	32.6
PCB #101 (penta)	ND (3.9)	47.1
PCB #99 (penta)	ND (3.2)	14.6
PCB #119 (penta)	ND (2.6)	ND (1.1)
PCB #87 (penta)	ND (3.9)	19.0
PCB #110 (penta)	ND (2.9)	21.6
PCB #123 (penta)	ND (2.4)	1.4
PCB #118 (penta)	NDR (4.3)	24.0
PCB #114 (penta)	ND (1.5)	ND (1.0)
PCB #105 (penta)	ND (1.6)	9.6
PCB #126 (penta)	ND (1.3)	ND (0.8)
PCB #155 (hexa)	ND (3.4)	ND (1.4)
PCB #151 (hexa)	ND (6.9)	NDR (7.9)
PCB #149 (hexa)	ND (6.1)	NDR (21.1)
PCB #153 (hexa)	7.9	30.9
PCB #168 (hexa)	ND (1.8)	NDR (6.7)
PCB #138 (hexa)	NDR (8.3)	27.6
PCB #158 (hexa)	ND (1.5)	ND (0.8)
PCB #128/#167 (hexa)	ND (1.6)	NDR (6.1)
PCB #156 (hexa)	ND (1.0)	4.3
PCB #157 (hexa)	ND (1.0)	ND (0.9)
PCB #169 (hexa)	ND (1.4)	ND (1.1)
PCB #188 (hepta)	ND (1.8)	ND (1.1)
PCB #179 (hepta)	ND (2.0)	ND (1.2)
PCB #178 (hepta)	ND (2.8)	ND (1.7)
PCB #187 (hepta)	ND (2.3)	NDR (6.7)
PCB #183 (hepta)	ND (2.5)	ND (1.5)
PCB #174 (hepta)	ND (1.7)	4.9
PCB #177 (hepta)	ND (1.7)	ND (1.2)
PCB #171 (hepta)	ND (1.6)	ND (1.1)
PCB #180 (hepta)	NDR (14.0)	12.6
PCB #191 (hepta)	ND (1.1)	ND (0.7)
PCB #170 (hepta)	ND (1.7)	7.2
PCB #189 (hepta)	ND (1.6)	ND (1.1)
PCB #202 (octa)	ND (1.5)	ND (1.3)
PCB #201 (octa)	ND (1.7)	ND (1.4)
PCB #200 (octa)	ND (1.7)	ND (1.4)
PCB #199 (octa)	ND (2.7)	ND (2.2)
PCB #203 (octa)	ND (2.4)	NDR (5.0)
PCB #195 (octa)	ND (1.7)	ND (1.4)
PCB #194 (octa)	ND (1.8)	ND (1.5)
PCB #205 (octa)	ND (1.3)	ND (1.1)
PCB #208 (nona)	ND (1.6)	ND (1.1)
PCB #206 (nona)	ND (2.5)	ND (1.7)
PCB #209 (deca)	ND (2.9)	NDR (2.6)
PCB #88 (penta)	ND (3.8)	ND (1.6)

2006-543-ENZ Table B: PCB Levels in Oil Sample (ppt)				
		Lab Blank	162-29D	
PCB CONGENER GROUP TOTALS		# of pks		# of pks
Mono-chloro-PCBs	4.5	1	108	3
Di-chloro-PCBs	*	0	961	1
Tri-chloro-PCBs	*	0	487	9
Tetra-chloro-PCBs	*	0	313	12
Penta-chloro-PCBs	*	0	177	9
Hexa-chloro-PCBs	7.9	1	73.8	5
Hepta-chloro-PCBs	*	0	24.8	3
Octa-chloro-PCBs	*	0	*	0
Nona-chloro-PCBs	*	0	*	0
Deca-chloro-PCB	*	0	*	0
TOTAL PCBs	ppt 12.4		2144	
	ppb 0.0124		2144	
	ppm 0.000124		0.002144	
WHO TEQs				
(ND=0)	0.00		0.01	
(ND=1/2*DL)	0.07		0.05	
(ND=DL)	0.15		0.10	
SURROGATE RECOVERIES				
13C - (3)	30		52	
13C - (15)	34		82	
13C - (28)	54		79	
13C - (52)	35		74	
13C - (70)	60		97	
13C - (77)	69		82	
13C - (101)	65		93	
13C - (118)	76		110	
13C - (105)	75		78	
13C - (126)	81		76	
13C - (153)	57		111	
13C - (138)	70		127	
13C - (167)	71		122	
13C - (178)	66		110	
13C - (156)	74		84	
13C - (169)	66		78	
13C - (180)	76		105	
13C - (170)	76		109	
13C - (189)	85		98	
13C - (194)	99		86	
13C - (206)	99		106	
13C - (209)	92		109	
* - ND (not detected, detection limits in brackets)				
NDR - none detected based on peak ratio (outside ± 20% of theoretical ratio)				
NDI - chemical interference				
NOTE: The following PCB isomers coelute and are reported together #4/#10, #126/#167, #90/#101, #170/#190				
Certain isomers may be reported at				
PCBs with higher degree of chlorination. These include the following list of PCBs. (The number in brackets represents the most likely candidate as an interference.)				
	#81 (#87)			
	#77 (#110)			
	#126 (#178, #129)			
	#156 (#171)			
	#157 (#201)			
	#123 (#149)			

Batch [REDACTED] – Pesticides



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2006-543-ENZ		
Table C : Organochlorine Pesticides in Oil (ng/g or PPB)		
	Lab Blank	162-29D
<b>ORGANOCHLORINE</b>		
a-BHC	ND(2)	ND(3)
HXCB	ND(1)	ND(2)
b-BHC	ND(3)	ND(5)
g-BHC (LINDANE)	ND(2)	ND(3)
d-BHC	ND(2)	ND(3)
HEPTACHLOR	ND(2)	ND(2)
OXYCHLORDANE	ND(2)	ND(2)
HEPTACHLOR EPOXIDE	ND(2)	ND(2)
o,p' DDE	ND(2)	ND(3)
g-CHLORDANE	ND(2)	ND(3)
a-CHLORDANE	ND(2)	ND(2)
t-NONACHLOR	ND(2)	ND(2)
p,p' DDE	ND(2)	ND(3)
o,p' DDD	ND(3)	ND(5)
p,p' DDD	ND(3)	ND(4)
o,p' DDT	ND(3)	ND(4)
c-NONACHLOR	ND(2)	ND(3)
p,p' DDT	ND(3)	ND(3)
MIREX	ND(2)	ND(3)
ND - none detected (detection limits in brackets)		
	<i>L. Tashiro</i>	November 6, 2006
	Analyst	Date

**SUBMISSION END**

**000033**