

GR



Original Submission

000008

GRAS Notification

Larex, Inc.
Arabinogalactan

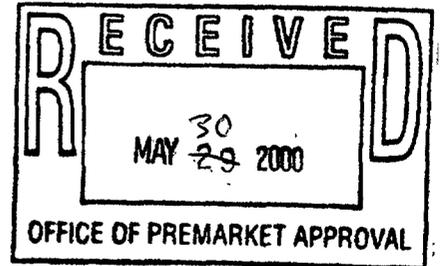
Manufactured by:

Larex, Inc.
4815 White Bear Lake Parkway
White Bear Lake, Minnesota
USA, 55110

Ph: 1-800-386-5300
Fax: 651-636-1583

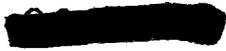
Prepared by:

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Austin, Texas 78724
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May 26, 2000

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LEE B. DEXTER & ASSOC.
TECHNOLOGY CONSULTANTS

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TELEPHONE (512) 276-7408
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May 26, 2000

Dr. Laura Tarantino
Acting Director
Office of Premarket Approval
Center for Food, Safety and Nutrition HFS 200
Food and Drug Administration
200 C St. SW
Washington, DC 20204

Dear Dr. Tarantino:

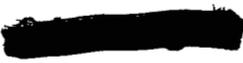
In accordance with the proposed rule for Substances Generally Recognized as Safe, which was published in the *Federal Register* at Vol. 62, No. 74 on April 17, 1997, Larex, Incorporated (Larex) of White Bear Lake, Minnesota submits a notice of a claim for exemption for the general use in foods of arabinogalactan. Arabinogalactan is a natural polysaccharide, which can be commercially extracted from trees of the Western larch *Larix occidentalis*, using water as the only solvent. Analytically, arabinogalactan is a soluble dietary fiber (80-85%) according to AOAC methods.

With this Notification Larex is incorporating by reference GRAS Notice No. 000017 dated October 15, 1998 and its amendments, and is providing additional information on exposure and specifications. A GRAS Report in support of the safe use of arabinogalactan in foods was prepared by Larex, and was reviewed on January 16, 1998 by a panel of experts qualified by training and experience. Those experts concurred with Larex's determination that arabinogalactan is safe for general use in foods.

On May 22, 2000 Larex personnel presented the salient points of the additional exposure and specification information to officials from the Center for Food Safety and Applied Nutrition (CFSAN), Office of Premarket Approval. At that time, the format for the attached notice of a claim for premarket exemption based on a GRAS determination under proposed §170.36 was discussed.

Larex has prepared a notification document in triplicate, which accompanies this letter. Larex would appreciate notice of the receipt of this document, and looks forward to the agency's concurrence that there is a sufficient basis for the GRAS determination of arabinogalactan.

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Page 2, Dr. Laura Tarantino

Thank you very much for your attention to this matter. If you have any questions regarding the content of the notification, you may reach me at the number listed above.

Sincerely,

Lee B. Dexter
Technical Consultant

CC: Dr. Linda Kahl, CFSAN
Dr. Michael DiNovi, CFSAN
Mr. Richard Faulkner, Larex
Mr. Robert Nickoloff, Larex
Mr. Richard Lamb, Larex

000011

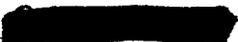


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Larex, Inc.
GRAS Notification
Arabinogalactan

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Larex Inc.
GRAS Notification for Arabinogalactan

Introduction

Arabinogalactan is a polysaccharide found in nature in the cell walls of most higher plants. As such, it has been consumed by humans as part of a normal diet for thousands of years. It is composed of galactose and arabinose units with a highly substituted back bone of β 1-3 linked galactopyranose units and side chains of galactose and arabinose. Larex, Inc. of White Bear Lake, Minnesota has developed a unique process to extract arabinogalactan from Western larch (*Larix occidentalis*) using only water as the solvent. Recently developed purification techniques have improved the product's visual and organoleptic properties, making it more desirable as a food ingredient. This Notification document and GRAS Notice 000017 dated October 15, 1998 and its amendments, which are incorporated herein by reference, contain the information required in proposed §170.36 to allow the FDA to evaluate whether the submitted notice provides a sufficient basis for a generally recognized as safe (GRAS) determination. This Notification provides the agency with additional information on exposure and specifications.

In compliance with 21 CFR § 170.30, Larex, Inc. determined that arabinogalactan can be considered GRAS when used in accordance with current Good Manufacturing Practices. Larex, Inc. wishes to voluntarily notify the FDA of that determination, and according to proposed § 170.36, the company is submitting the following GRAS exemption claim.

Larex, Inc. has prepared a twelve-volume GRAS Report, which forms the basis for the information found in this Notification and in GRAS Notice 000017. The company commissioned a panel of experts, qualified by scientific training and experience to assess the safety of food ingredients, which critically evaluated the arabinogalactan GRAS Report as well as other data and information relevant to the use and safety of this ingredient. In a meeting held on January 16, 1998, the panel concurred with the company's determination that Larex Inc.'s arabinogalactan can be considered generally recognized as safe for general use in food. Based on the data and information contained in the Report and the opinion of the expert panel (which was attached to GRAS Notice 000017), Larex, Inc. explicitly accepts responsibility for the GRAS determination of arabinogalactan.

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GRAS Exemption Claim

Larex, Inc. hereby notifies the U.S. Food and Drug Administration that the use of arabinogalactan as a food ingredient is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act, because Larex, Inc. has determined that such use is GRAS.

1. Notifier:

Larex Inc.
4815 White Bear Lake Parkway
White Bear Lake, Minnesota USA 55110
Telephone: (800) 386-5300
Fax: (651) 636-1583

2. Common or Usual Name:

Arabinogalactan

3. Applicable Conditions of Use:

Applications for arabinogalactan include general use in foods as a multiple-use direct additive. The ingredient should be used under the conditions of current Good Manufacturing Practice. In order to classify the various effects ingredients may have in food, FDA has published a list of 32 physical or technical functional effects for which direct food ingredients may be added to food. These are codified at 21 CFR §170.3 (o) (1-32). Applications for arabinogalactan are covered under several of the following terms as listed under 21 CFR §170.3 (o).

(8) "Emulsifiers and emulsifier salts": Substances which modify surface tension in the component phase of an emulsion to establish a uniform dispersion or emulsion.

(14) "Formulation aids": Substances used to promote or produce a desired physical state or texture in food, including carriers, binders, fillers, plasticizers, film-formers, and tableting aids, etc.

(16) "Humectants": Hygroscopic substances incorporated in food to promote retention of moisture, including moisture-retention agents and antidusting agents.

Notification Claim (Continued)

(20) "Nutrient supplements": Substances which are necessary for the body's nutritional and metabolic processes.

(24) "Processing aids": Substances used as manufacturing aids to enhance the appeal or utility of a food or food component, including clarifying agents, clouding agents, catalysts, flocculants, filter aids, and crystallization inhibitors, etc.

(28) "Stabilizers and thickeners": Substances used to produce viscous solutions or dispersions, to impart body, improve consistency, or stabilize emulsions, including suspending and bodying agents, setting agents, jellying agents, and bulking agents, etc.

(31) "Synergist": Substances used to act or react with another food ingredient to produce a total effect different or greater than the sum of the effects produced by the individual ingredients.

(32) "Texturizers": Substances which affect the appearance or feel of the food.

4. Basis of the GRAS Determination

The basis of the GRAS determination for Larex Inc. arabinogalactan was the use of scientific procedures.

5. Availability of Data and Information and Key to References

The data and information that are the basis of the GRAS determination for Larex Inc. arabinogalactan will be available at the address of the notifier listed above and in Food Additive Master File No. 617. Throughout this Notification, citations to the published literature, which were included in the 12-volume GRAS Report are denoted as follows: [Author (*et al*), Year, Tab (number) Volume (number)]. Larex, Inc. will be pleased to provide the agency copies of any of the references or other information pertinent to this GRAS Notification upon written request.

Notification Claim (Continued)

6. Signature of an official for Larex, Inc.

Date

Lee B. Dexter, Technical Consultant

May 26, 2000

A Realistic Estimate of Exposure to Arabinogalactan

Larex, Inc. was asked to provide the FDA with a realistic estimate of exposure to arabinogalactan. The agency's guidance document "*Estimating Exposure to Direct Food Additives and Chemical Contaminants in the Diet*" and USDA's *Continuing Survey of Food Intakes by Individuals* (CSFII, 1996) were used as references to estimate the realistic exposure to the arabinogalactan produced by Larex, Inc. [Enns, *et al.*, 1997].

USDA's CSFII, 1996 was used to estimate mean intakes of the various food categories. Realistic usage levels of arabinogalactan were assigned based on industry experience, applications trials, and economic considerations. The contribution of each food category to arabinogalactan exposure was calculated by multiplying the average usage level of arabinogalactan for recognized food subcategories by the average consumption for men and women as reported by the CSFII, 1996. This value was considered to be the mean level of intake.

In order to calculate the 90th percentile of consumption, the mean intake level was multiplied by 2 as indicated the agency's guidance document. Additional exposure to arabinogalactan may result from its use as a source of soluble prebiotic fiber in dietary supplement form [Enns, *et al.*, 1997 and Causey, *et al.*, 1999]. Recommended dosages for arabinogalactan as a prebiotic fiber have been determined by clinical trial [Causey, *et al.*, 1999].

While the percentage of use assigned to each food subcategory was considered realistic, the exposure estimate remained conservative because 100% market penetration was assumed, and arabinogalactan was assumed to be included in all products in a given subcategory. Additionally, the values presented below assume that 100% of consumers are "eaters" of arabinogalactan containing products.

In reality, arabinogalactan is expected to be used in only certain products within a given subcategory. Further, use within a subcategory will be limited by economics and organoleptic considerations. Market development in the US is likely to be directed towards the functional properties of arabinogalactan, and certain functional properties may not be appropriate for a given consumer product. An example of this is that arabinogalactan tends to reduce viscosity in batter or fluid food systems. This may not create a desirable product in all cases.

Arabinogalactan Exposure Continued

Additionally, Larex, Inc. arabinogalactan is a very expensive food ingredient, costing several dollars per pound. Therefore, those applications in which it will be cost effective will need to be carefully chosen, and will most likely dictate that arabinogalactan will be used at the minimum level necessary to produce a given technical or nutritional effect.

Table 1 below shows the realistic percentages of use assigned to each of the forty-three food categories listed at 21 CFR § 170.3 (n). The correlation between the major food categories derived from the USDA food survey, and those listed at § 170.3 (n) is shown in Table 3.

The mean intake for selected major food subcategories is shown in Table 2 below. The sum of the grams of arabinogalactan calculated from the mean intakes for each major food category listed on Table 2 is 10.474 grams per day. The agency's guidance document indicates that an estimate of the 90th percentile level of intake can be calculated by doubling the total mean intake. This value is 20.95 grams per day. Larex, Inc. is also aware that certain individuals may consume arabinogalactan as a dietary supplement. The recommended dose of arabinogalactan as a dietary supplement is 4.5 grams per day. This dosage has been recommended based on the results of clinical trials with human volunteers [Causey, *et al.*, 1999 and Kim, *et al.*, 1999].

Interestingly, the CSFII, 1996 shows that the mean fiber intake averaged for men and women is 16.1 grams per day [Enns, *et al.*, 1997]. This level is still well below the 25-30 grams per day recommended by many health agencies. The addition of arabinogalactan to the diet, therefore, is not expected to create excessive fiber intake.

Larex, Inc. submits, therefore, that exposure to arabinogalactan will not result in a harmful level of fiber intake, and that arabinogalactan is safe for its intended use as a food ingredient.

**Table Maximum Use of Larex Arabinogalactan
In the Food Categories Listed by the US FDA
At 21 CFR §170.3 (n)**

	Food Categories	Realistic Percentage of Use in the US Market*
01	Baked Goods, Baking Mixes	1.72%
02	Beverages alcoholic	0
03	Beverages and beverage bases, non-alcoholic	2.0%
04	Breakfast Cereals	1.7%
05	Cheeses	1.0%
06	Chewing Gum	0.278%
07	Coffee and tea**	2.0%
08	Condiments and relishes	5.65%
09	Confections and frostings	3.16%
10	Dairy product analogs	0
11	Egg Products	0.5%
12	Fats and oils	1.0%
13	Fish Products	0
14	Fresh eggs	0
15	Fresh fish	0
16	Fresh fruits and fruit juices	4.0%
17	Fresh Meats	0.2%
18	Fresh poultry	0.2
19	Fresh vegetables	0
20	Frozen dairy desserts and mixes	0.313%
21	Fruit and water ices	2.0%
22	Gelatins, puddings and fillings	1.5%
23	Grain products and pastas	0.166%
24	Gravies and Sauces	0.25%
25	Hard candy	2.72%
26	Herbs, seeds, spices, seasonings, blends	20.0%
27	Jams and jellies, home prepared	0
28	Jams and jellies commercial	5.0%
29	Meat products	0.2%
30	Milk, whole and skim	0
31	Milk products	1.5%
32	Nuts and Nut products	0
33	Plant protein products	0
34	Poultry products	0.2%
35	Processed fruits and fruit juices	4.0%
36	Processed vegetables and vegetable juices	0.214%
37	Snack foods	0.5%
38	Soft Candy	2.72%
39	Soups, home prepared	0
40	Soups and soup mixes	1.16%
41	Sugar, white granulated	0
42	Sugar substitutes	16.0%
43	Sweet Sauces, toppings, and syrups	1.25%

Table 2
Estimated Intake of Arabinogalactan in Selected Food Categories

Major Food Codes	Food Category	Use level (%)	Food Intake (g)	AG Intake (g)	CSFII
	Baked goods, baking mixes				
51	Yeast Breads and Rolls	0.5	50	0.25	1996
52, 55	Quick breads, pancakes, etc.	0.5	0.1	0.694	1996
53	*Cakes, cookies, pastries, pies	3.75	38	1.42	1996
58	Mixtures mainly grain	0.5	107	0.535	1996
	Breakfast cereals				
571 - 574, 578	Ready-to-eat cereals	1.7	17	0.289	1996
	Grain products and pastas				
562	Rice	0	19	0	1996
561	Pasta	0.5	21	0.105	1996
54	Snack foods(crackers, chips)	0.25	12	0.3	1996
	Total Vegetables		132		1996
	Fresh vegetables	0	0	0	1996
	Processed vegetables, juices	0	0	0	1996
	Total Fruits		162		1996
612	Citrus juices	1	59	0.59	1996
621	Dried fruits	0	1	0	1996
641,642	Non-citrus juices and nectars	1	26	0.26	1996
	Fruits and mixtures	0	0	0	1996
	Milk products				
114	Yogurt	4	8	0.32	1996
131,132, 133, 134	Milk desserts	0.725	24	0.174	1996
140-147	Cheese	1	16	0.16	1996
116, 118	Milk-Based Beverages	4	34	1.36	1966
	Meat Products				
252	Sausages, processed meats	0.2	21	0.42	1996
271,272,273,274	Mixtures mainly meat	0.2	99	0.198	1996
	Eggs				
321,323,324, 33,34	Egg Products	0.5	9**	0.045	1996
	Legumes				
	Legumes	0	0	0	1996
	Nuts and Nut Products				
	Nuts and Nut Products	0	0	0	1996
	Fats and Oils				
832	Salad dressings	0.25	8	0.02	1996
	Total sugars and sweets				
917,918	Candy (Soft and Hard)	2.72	7	0.19	1996
911 - 916	Other Sugar Products***	3.16	15	0.474	1996
	Beverages Non-Alcoholic				
	Coffee	0	254	0	1996
923	Teas	2	128	2.56	1996
925	Low Cal.Fruit drinks and ades	2	18	0.36	1996
92400100	Low Cal. Carbonated drinks	2	74	1.48	1996
	Total Intake (grams)			10.474	
	Dietary Supplement			4.5	
	* Includes dietetic bars				
	** Includes 50% of egg intake for processed eggs				
	*** Includes Jams, Jellies, etc.				

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Table 3
USDA Major Food Categories
And Corresponding Categories
From 21 CFR 170.3 (n)

USDA Food Category ¹	Categories Listed In 170.3 (n) ²
Total Grain Products	01, 04, 23, 37
Dietary Supplement; Source of Soluble Fiber	
Vegetables and Vegetable Dishes	36
Fruits and Fruit Preparations	16, 35
Milk Desserts/Cheese Products	5, 20, 22, 31, 10
Meat, Poultry and Fish	29, 34
Total Fats and Oils	12
Legumes and Legume Dishes	33, 36
Sugars and Sweets	06, 09, 25, 28, 38, 42, 43
Nuts and Seeds	32
Total Non-Alcoholic Beverages (excluding coffee and fruit juices)	16, 35, 03

1. Major food categories are those used in USDA's Continuing Survey of Food Intake by Individuals [Enns, *et al.*, 1997].
2. Column 2 contains the number assigned to the various food categories as listed in 21 CFR § 170.3 (n), which are contained within those reported by Enns, *et al.*, 1997 [Enns, *et al.*, 1997].

Revised Specifications

In accordance with discussions with agency personnel, Larex wishes to provide revised specifications for its arabinogalactan products. Recent analyses for lead allow a specification of < 0.1 ppm for all food-grade products.

Tables 1 and 2 below demonstrate that lead levels for a variety of arabinogalactan products are either below the level of detection, or well below 0.1 ppm. Table 1 depicts lead data from raw arabinogalactan extract from Western larch (*Larix occidentalis*). Table 2 summarizes lead data from arabinogalactan products, which have received further processing. Detection limits are shown on each table.

Table 1

Larex Arabinogalactan	
Lead Levels	
Lots	Results
2-T3-99279-01	0.023 ppm Aver.
001B-97155-03	Non-detectable
Western Larch	Lots of LSC-1
Duplicate Samples	Detection Limit 0.008 ppm

Table 2

Lead Levels	
Larex Arabinogalactan	
Product	Aver. (ppm)
Decolorized	0.051 999022)
Decolorized	0.023 (99284)
CT AG 99*	N.D (00054)
CT 99*	N.D. (99108)
CT 99*	N.D. (99358)
Grade 100-Dried**	0.052 (00054)
	D.L. = 0.020

* CT has been identified in GRN 000017 as Fiberaid.

** Grade 100 has been identified as LSC-1. However, Grade 100 has been dried.

Revised specifications appear below for decolorized and the LSC-1 (mother liquor) product.

Final Product Specifications for Larex Decolorized Arabinogalactan

Food Grade	
Chemical Specifications	
Arabinogalactan	>90% (d.w.b.)
Total Ash	<10%
Bulk Density	<0.75 g/ml
Chloride	<1,500 ppm
Lead	<0.1 ppm
Insoluble Matter	<0.1%
Molecular Weight	16,000 – 25,000
pH	4.0 – 8.0
Phenol	<5.0 ppm
UV 280 nm	0.5 – 2.0
Viscosity	<5.0 cps
Microbiological Specifications	
Aerobic Plate Count	<1,000 CFU
<i>Salmonella sp.</i>	Negative
<i>Staphylococci sp.</i> (coagulase positive)	< 10 CFU
<i>Eschericia coli</i>	<10 CFU
Yeast	<100 CFU
Mold	<100 CFU

Final Product Specifications for Larex Arabinogalactan LSC-1

Food Grade Chemical Specifications	
Arabinogalactan	50-55%
Total Ash	<5%
Bulk Density	<0.75 g/ml
Chloride	<150 ppm
Lead	<0.1 ppm
Insoluble Matter	<0.1%
Molecular Weight	16,000 – 25,000
pH	3.0 – 6.0
Phenol	1.0 – 3.0 ppm
UV 280 nm	0.55 – 1.20
Viscosity	<500 cps
<u>Microbiological Specifications</u>	
Aerobic Plate Count	<1,000 CFU
<i>Salmonella sp.</i>	Negative
<i>Staphylococci sp.</i> (coagulase positive)	< 10 CFU
<i>Eschericia coli</i>	<10 CFU
Yeast	<100 CFU
Mold	<100 CFU

Tables 3 and 4 below provide a key to the applicable specifications for each of the Larex, Inc. arabinogalactan products.

Table 3
LAREX Arabinogalactan Products

Arabinogalactan Product Name	Market and Properties of Products	Applicable Specification
LaraPrint™ B50	Ink additive for decreasing viscosity while maintaining color density: caramel colored 50% solution preserved with potassium sorbate.	LSC-1
LaraPrint™ B100	Ink additive for decreasing viscosity while maintaining color density: tan colored powder	LSC-1
L'Extra™ F100	A fiber source: off-white powder, very low taste and odor, no precipitation in liquids, excellent dissolution.	LSC-1 (pre-drying)
LaraCare™ A200	Emulsion stabilizer, film and gloss former, dispersant, moisture control, rheology control: off-white powder, mild odor, highly soluble, excellent dissolution, and biodegradable.	Decolorized
L'Extra™ F2000	Moisture control: mouthfeel, encapsulation, bulking agent: off-white powder, low viscosity, very low taste and odor, some precipitation in liquids, excellent dissolution, used for moisture control.	Decolorized
FIBERAID™ ClearTrac™ (CT)	A fiber source: off-white powder, very low taste and odor, no precipitation in liquids, excellent dissolution.	Decolorized

Table 4
LAREX Product Specific Processing Steps

Arabinogalactan Product Name	Processing Steps
LaraPrint™ B50	extraction, screening, separation, evaporation, preservative addition
LaraPrint™ B100	extraction, screening, separation, evaporation, preservative addition, spray drying
L'Extra™ F100	extraction, screening, separation, evaporation, preservative addition, spray drying
LaraCare™ A200	extraction, screening, separation, evaporation, decolorizing, ion exchange, spray drying, agglomeration
L'Extra™ F2000	extraction, screening, separation, evaporation, decolorizing, carbon filtering, spray agglomeration
FIBERAID™ ClearTrac™ (CT)	extraction, separation, evaporation, decolorizing, carbon filtering, ion exchange, spray agglomeration

Summary

Larex Inc. has provided realistic exposure data, demonstrating that potential consumption of arabinogalactan will not reach levels of toxicological concern. Further, the specifications have been revised to reflect greater purity.

Larex, Inc. therefore submits that its arabinogalactan products can be considered generally recognized as safe, when used in accordance with current Good Manufacturing Practices.



WEST COAST
ANALYTICAL
SERVICE, INC.
Analytical Chemists

November 17, 1999

Larex
4815 White Bear Parkway
White Bear Lake, MN 55110-3325

Attn: Lori Siegler

Job No: 44433

PH

LABORATORY REPORT

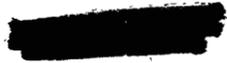
Samples Received: Three (3) Samples
Date Received: 11-09-99
Purchase Order No: 5645

The samples were analyzed as follows:

<u>Analysis</u>	<u>Page</u>
Lead per CA AG Protocol for Proposition 65 by ICPMS	2

Michael Shelton
Senior Staff Chemist

Charles Jacks, Ph.D.
Senior Staff Chemist



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Page 1 of 2

re
tr Mori Siegler

Job No: 44433
November 17, 1999

LABORATORY REPORT

Lead per CA AG Protocol for Proposition 65
Quantitative Analysis Report
Inductively Coupled Plasma-Mass Spectrometry

Sample ID	Parts Per Million (ug/g)		
	Rep 1	Rep 2	Avg.
ImmunEnhancer AG			
LA-99284-01	0.019	0.015	0.017
LA-99022-01	0.041	0.039	0.040
LA-99143-01	ND	ND	ND

Detection Limit: 0.010
Date Analyzed: 11-15-99

Quality Control Summary

Sample: ImmunEnhancer AG 2-LA-99143-01

Lead
Parts Per Million (ug/g)

Sample:	ND
Duplicate:	ND
Average:	ND
Sample RPD:	NR
Spike Conc:	1.04
Spike Result:	1.00
Recovery	96.0

Control Limits:
ND <25%
Recovery 80-120%

Date Analyzed: 11-15-99

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WCAS

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WEST COAST
ANALYTICAL
SERVICE, INC.
Analytical Chemists

April 24, 2000

Larex
4815 White Bear Parkway
St Paul, MN 55110-3325

Attn: Bryan Rodriguez

Job No: 46564

DL

LABORATORY REPORT

Samples Received: Thirteen (13) Samples
Date Received: 04/12/2000
Purchase Order No: CREDIT CARD

The samples were analyzed as follows:

<u>Analysis</u>	<u>Page</u>
Lead per CA AG Protocol for Proposition 65 by ICPMS	2 - 3

D. J. Northington, Ph.D.
Quality Assurance Officer

Charles Jacks, Ph.D.
Senior Staff Chemist

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Page 1 of 3

Corex
 Attn: Bryan Rodriguez

Job No: 46564
 April 24, 2000

Lead per CA AG Protocol for Proposition 65
 Quantitative Analysis Report
 Inductively Coupled Plasma-Mass Spectrometry

Parts Per Million ($\mu\text{g/g}$)

<u>Sample ID</u>	<u>Rep 1</u>	<u>Rep 2</u>	<u>Avg.</u>
2-LA-99022-01	0.055	0.047	0.051
2-LA-99284-01	0.020	0.025	0.023
2-A2-99152-01	0.086	0.082	0.084
2XP9910801	ND	ND	ND
2C99935801	ND	ND	ND
2C19800501	* 0.051	0.052	0.052
2C90005401	* ND	ND	ND
Grade 100 Tamarack	ND	ND	ND
ClearTrac Tamarack	ND	ND	ND
LaraCare Tamarack	ND	ND	ND
ImmunEnh. Tamarack	ND	ND	ND

Detection Limit: 0.020

Date Analyzed: 4-17-00, * 4-19-00

Quality Control Summary

Sample: SRM 1486 Bone Meal

		<u>Certified</u>		<u>%</u>	
	<u>Mass</u>	<u>Value</u>	<u>Found</u>	<u>Acceptable</u>	<u>%</u>
		<u>$\mu\text{g/g}$</u>	<u>$\mu\text{g/g}$</u>	<u>Error</u>	<u>Error</u>
Lead	206-8	1.335	1.320	20	-1.1%

Date Analyzed: 4-19-00

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This report is to be reproduced in its entirety.

WCAS

Larex
Attn: Bryan Rodriguez

Job No: 46564
April 24, 2000

Lead per CA AG Protocol for Proposition 65
Quantitative Analysis Report
Inductively Coupled Plasma-Mass Spectrometry

<u>Sample ID</u>	<u>Parts Per Million ($\mu\text{g/g}$)</u>		
	<u>Rep 1</u>	<u>Rep 2</u>	<u>Avg.</u>
2-T3-99279-01	0.023	0.024	0.023
0018-97155-03	ND	ND	ND

Detection Limit: 0.008

Date Analyzed: 4-17-00

Quality Control Summary

Sample: 2C99935801

	<u>Lead</u> <u>Parts Per Million ($\mu\text{g/g}$)</u>
Sample:	ND
Duplicate:	ND
Average:	ND
Sample RPD:	NR
Spike Conc:	0.98
MS Result:	0.960
% Recovery	97.9
Control Limits:	
RPD	<25%
% Recovery	80-120%

Date Analyzed: 4-17-00

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This report is to be reproduced in its entirety.

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Submission End

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