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AR-17-QD-097226-01

Eurofins Sample Code: 464-2017-06080320
Client Sample Code: Accelerated-Month 1 CSPBWL-170308

Test	Result	
QD00T - Visual Appearance- Other		**Completed: 06/12/2017**
Internal Method		
Appearance	-	
Fine, dark green powder containing smaller, darker green flecks. Slight grassy aroma. No off-odors.		
QD089 - Fatty Acids-Omega 6 & 3 %W/W		**Completed: 06/15/2017**
AOCS Ce 2-66 AOCS Ce 1-62		
* Fatty Acid Profile, % Weight	Reported as Fatty Acids	
* C08:0 Octanoic (Caprylic)	<0.01 %	
* C10:0 Decanoic (Capric)	<0.01 %	
* C11:0 Undecanoic (Hendecanoic)	<0.01 %	
* C12:0 Dodecanoic (Lauric)	<0.01 %	
* C14:0 Tetradecanoic (Myristic)	0.03 %	
* C14:1 Tetradecenoic (Myristoleic)	<0.01 %	
* C15:0 Pentadecanoic	0.05 %	
* C15:1 Pentadecenoic	<0.01 %	
* C16:0 Hexadecanoic (Palmitic)	1.25 %	
* C16:1 Hexadecenoic (Palmitoleic)	0.24 %	
* C16:2 Hexadecadienoic	<0.01 %	
* C16:3 Hexadecatrienoic	<0.01 %	
* C16:4 Hexadecatetraenoic	<0.01 %	
* C17:0 Heptadecanoic (Margaric)	0.01 %	
* C17:1 Heptadecenoic (Margaroleic)	0.01 %	
* C18:0 Octadecanoic (Stearic)	0.06 %	
* C18:1 Octadecenoic (Oleic)	0.13 %	
* C18:2 Octadecadienoic (Linoleic)	1.16 %	
* C18:2 Octadecadienoic Omega 6	1.14 %	
* C18:3 Octadecatrienoic (Linolenic)	3.50 %	
* C18:3 Octadecatrienoic Omega 3	3.41 %	
* C18:3 Octadecatrienoic Omega 6	0.09 %	
* C18:4 Octadecatetraenoic	0.25 %	
* C18:4 Octadecatetraenoic Omega 3	0.25 %	
* C20:0 Eicosanoic (Arachidic)	0.03 %	
* C20:1 Eicosenoic (Gondoic)	<0.01 %	
* C20:2 Eicosadienoic	0.01 %	
* C20:2 Eicosadienoic Omega 6	0.01 %	
* C20:3 Eicosatrienoic	0.01 %	
* C20:3 Eicosatrienoic Omega 3	0.01 %	
* C20:3 Eicosatrienoic Omega 6	<0.01 %	
* C20:4 Eicosatetraenoic (Arachidonic)	<0.01 %	
* C20:4 Eicosatetraenoic Omega 3	<0.01 %	
* C20:4 Eicosatetraenoic Omega 6	<0.01 %	
* C20:5 Eicosapentaenoic	<0.01 %	
* C20:5 Eicosapentaenoic Omega 3	<0.01 %	
* C21:5 Heneicosapentaenoic	<0.01 %	
* C21:5 Heneicosapentaenoic Omega 3	<0.01 %	
* C22:0 Docosanoic (Behenic)	0.04 %	
* C22:1 Docosenoic (Erucic)	<0.01 %	
* C22:2 Docosadienoic	<0.01 %	
* C22:2 Docosadienoic Omega 6	<0.01 %	
* C22:3 Docosatrienoic	<0.01 %	
* C22:3 Docosatrienoic, Omega 3	<0.01 %	
* C22:4 Docosatetraenoic	<0.01 %	
* C22:4 Docosatetraenoic Omega 6	<0.01 %	
* C22:5 Docosapentaenoic	<0.01 %	
* C22:5 Docosapentaenoic Omega 3	<0.01 %	

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AR-17-QD-097226-01

Eurofins Sample Code: 464-2017-06080320
Client Sample Code: Accelerated-Month 1 CSPBWL-170308

Test	Result	
QD089 - Fatty Acids-Omega 6 & 3 %W/W (Cont.)		**Completed: 06/15/2017**
AOCS Ce 2-66 AOCS Ce 1-62		
* C22:5 Docosapentaenoic Omega 6	<0.01 %	
* C22:6 Docosahexaenoic	<0.01 %	
* C22:6 Docosahexaenoic Omega 3	<0.01 %	
* C24:0 Tetracosanoic (Lignoceric)	0.08 %	
* C24:1 Tetracosenoic (Nervonic)	<0.01 %	
* Sum of Omega 3 Isomers	3.68 %	
* Sum of Omega 6 Isomers	1.24 %	
* Total Fatty Acids Calc.	6.89 %	
UM7MY - Total Aerobic Microbial Count - USP Chapter <61>		**Completed: 06/14/2017**
U.S. Pharmacopeia Chapter 61		
Total Aerobic Microbial Count	4,200 cfu/g	
UMR5L - Moulds - USP Chapter <61>		**Completed: 06/14/2017**
U.S. Pharmacopeia Chapter 61		
Mold	< 10 cfu/g	
Yeast	< 10 cfu/g	
Yeast & Moulds	< 10 cfu/g	
QQ167 - Water Activity		**Completed: 06/12/2017**
AOAC 978.18		
* Water Activity at 25°C	0.054	
SK06I - Hexanal and Propanal		**Completed: 07/03/2017**
No Reference		
Hexanal	3.5 mg/kg	
Propanal	10.7 mg/kg	

**The test result is covered by our current A2LA accreditation.*

Respectfully Submitted,
Eurofins Scientific Inc.

(b) (6)

David Gross
Support Services Manager

A2LA ACCREDITED Biological Testing Cert:3329:01

A2LA ACCREDITED Chemical Testing Cert:2927:01

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Eurofins Scientific, Inc. Measurement of Uncertainty can be obtained upon request.

Accelerated Month 3 Results (Time 3) for 4 LENTEIN Complete batches:

eurofins | Nutrition Analysis Center

Eurofins Scientific Inc.
Nutrition Analysis Center
2200 Rittenhouse Street, Suite 150
Des Moines, IA 50321
Tel:+1 515 265 1461
Fax:+1 515 266 5453

Eurofins Sample Code: 464-2017-07050161
Sample Description: Stability Study #1281 – Lentein Complete
Client Sample Code: Accelerated - Month 3 - CSPBWL-170207
PO Number: V85R20170044
Client Code: QD0007548

Entry Date: 07/05/2017
Reporting Date: 07/21/2017

Parabel USA Inc.
attn: Valentina Carpio
7898 S. Headwaters Commerce St. Bldg 3
Fellsmere, FL 32948

Parabel USA Inc.
Attn: Ebenezer Ifeduba
14655 101 Street
Fellsmere, Florida 32948

CERTIFICATE OF ANALYSIS

AR-17-QD-105539-01

Test	Result	
QD252 - Protein - Combustion		**Completed: 07/10/2017**
AOAC 990.03; AOAC 992.15		
* Protein	42.77 %	
QD148 - Moisture by Vacuum Oven		**Completed: 07/10/2017**
AOAC 925.09		
* Moisture and Volatiles - Vacuum Oven	1.5 %	
QD172 - pH		**Completed: 07/06/2017**
AOAC 981.12		
pH	6.88	
QQ141 - Tryptophan (AOAC, Most Matrices)		**Completed: 07/13/2017**
AOAC 988.15		
* Tryptophan	0.92 %	
QQ177 - Cystine & Methionine (AOAC, Most Matrices)		**Completed: 07/14/2017**
AOAC 994.12 mod.		
* Cystine	0.47 %	
* Methionine	0.89 %	
QQ176 - Amino Acids by AH (AOAC, Most Matrices)		**Completed: 07/10/2017**
AOAC 982.30 mod.		
* Alanine	2.48 %	
* Arginine	2.74 %	
* Aspartic Acid	3.97 %	
* Glutamic Acid	4.59 %	
* Glycine	2.30 %	
* Histidine	0.95 %	
* Isoleucine	2.09 %	
* Leucine	3.85 %	
* Phenylalanine	2.40 %	
* Proline	2.00 %	
* Serine	1.97 %	
* Threonine	1.96 %	
* Total Lysine	2.84 %	
* Tyrosine	1.52 %	
* Valine	2.63 %	
QD07G - Peroxide Value with Extraction (AOCS)		**Completed: 07/06/2017**
AOCS Cd 8-53		
* Peroxide value	4.1 meq/kg fat	

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AR-17-QD-105539-01

Eurofins Sample Code: 464-2017-07050161
Client Sample Code: Accelerated - Month 3 - CSPBWL-170207

Test	Result	
QD00T - Visual Appearance- Other		**Completed: 07/07/2017**
Internal Method		
Appearance	-	
Fine, vibrant green powder containing smaller, darker green flecks. Prominent grassy aroma. No off-odors.		
QD089 - Fatty Acids-Omega 6 & 3 %W/W		**Completed: 07/11/2017**
AOCS Ce 2-66 AOCS Ce 1-62		
* Fatty Acid Profile, % Weight	Reported as Fatty Acids	
* C08:0 Octanoic (Caprylic)	<0.01 %	
* C10:0 Decanoic (Capric)	<0.01 %	
* C11:0 Undecanoic (Hendecanoic)	<0.01 %	
* C12:0 Dodecanoic (Lauric)	<0.01 %	
* C14:0 Tetradecanoic (Myristic)	0.05 %	
* C14:1 Tetradecenoic (Myristoleic)	<0.01 %	
* C15:0 Pentadecanoic	0.06 %	
* C15:1 Pentadecenoic	<0.01 %	
* C16:0 Hexadecanoic (Palmitic)	1.41 %	
* C16:1 Hexadecenoic (Palmitoleic)	0.29 %	
* C16:2 Hexadecadienoic	<0.01 %	
* C16:3 Hexadecatrienoic	<0.01 %	
* C16:4 Hexadecatetraenoic	<0.01 %	
* C17:0 Heptadecanoic (Margaric)	0.02 %	
* C17:1 Heptadecenoic (Margaroleic)	0.02 %	
* C18:0 Octadecanoic (Stearic)	0.07 %	
* C18:1 Octadecenoic (Oleic)	0.16 %	
* C18:2 Octadecadienoic (Linoleic)	1.22 %	
* C18:2 Octadecadienoic Omega 6	1.19 %	
* C18:3 Octadecatrienoic (Linolenic)	3.49 %	
* C18:3 Octadecatrienoic Omega 3	3.39 %	
* C18:3 Octadecatrienoic Omega 6	0.10 %	
* C18:4 Octadecatetraenoic	0.29 %	
* C18:4 Octadecatetraenoic Omega 3	0.29 %	
* C20:0 Eicosanoic (Arachidic)	0.03 %	
* C20:1 Eicosenoic (Gondoic)	0.05 %	
* C20:2 Eicosadienoic	<0.01 %	
* C20:2 Eicosadienoic Omega 6	<0.01 %	
* C20:3 Eicosatrienoic	0.02 %	
* C20:3 Eicosatrienoic Omega 3	0.02 %	
* C20:3 Eicosatrienoic Omega 6	<0.01 %	
* C20:4 Eicosatetraenoic (Arachidonic)	<0.01 %	
* C20:4 Eicosatetraenoic Omega 3	<0.01 %	
* C20:4 Eicosatetraenoic Omega 6	<0.01 %	
* C20:5 Eicosapentaenoic	0.01 %	
* C20:5 Eicosapentaenoic Omega 3	0.01 %	
* C21:5 Heneicosapentaenoic	<0.01 %	
* C21:5 Heneicosapentaenoic Omega 3	<0.01 %	
* C22:0 Docosanoic (Behenic)	0.05 %	
* C22:1 Docosenoic (Erucic)	<0.01 %	
* C22:2 Docosadienoic	<0.01 %	
* C22:2 Docosadienoic Omega 6	<0.01 %	
* C22:3 Docosatrienoic	<0.01 %	
* C22:3 Docosatrienoic, Omega 3	<0.01 %	
* C22:4 Docosatetraenoic	<0.01 %	
* C22:4 Docosatetraenoic Omega 6	<0.01 %	
* C22:5 Docosapentaenoic	<0.01 %	
* C22:5 Docosapentaenoic Omega 3	<0.01 %	

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AR-17-QD-105539-01

Eurofins Sample Code: 464-2017-07050161
Client Sample Code: Accelerated - Month 3 - CSPBWL-170207

Test	Result	
QD089 - Fatty Acids-Omega 6 & 3 %W/W (Cont.)		**Completed: 07/11/2017**
AOCS Ce 2-66 AOCS Ce 1-62		
* C22:5 Docosapentaenoic Omega 6	<0.01 %	
* C22:6 Docosahexaenoic	0.01 %	
* C22:6 Docosahexaenoic Omega 3	0.01 %	
* C24:0 Tetracosanoic (Lignoceric)	0.09 %	
* C24:1 Tetracosenoic (Nervonic)	<0.01 %	
* Sum of Omega 3 Isomers	3.72 %	
* Sum of Omega 6 Isomers	1.31 %	
* Total Fatty Acids Calc.	7.35 %	
UM7MY - Total Aerobic Microbial Count - USP Chapter <61>		**Completed: 07/11/2017**
U.S. Pharmacopeia Chapter 61		
Total Aerobic Microbial Count	1,600 cfu/g	
UMR5L - Moulds - USP Chapter <61>		**Completed: 07/11/2017**
U.S. Pharmacopeia Chapter 61		
Mold	< 10 cfu/g	
Yeast	< 10 cfu/g	
Yeast & Moulds	< 10 cfu/g	
QQ167 - Water Activity		**Completed: 07/07/2017**
AOAC 978.18		
* Water Activity at 25°C	0.046	
SK06I - Hexanal and Propanal		**Completed: 07/20/2017**
No Reference		
Hexanal	7.1 mg/kg	
Propanal	8.0 mg/kg	

**The test result is covered by our current A2LA accreditation.*

Respectfully Submitted,
Eurofins Scientific Inc.

(b) (6)

David Gross
Support Services Manager

A2LA ACCREDITED Biological Testing Cert:3329:01
A2LA ACCREDITED Chemical Testing Cert:2927:01

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Eurofins Scientific Inc.
Nutrition Analysis Center
2200 Rittenhouse Street, Suite 150
Des Moines, IA 50321
Tel:+1 515 265 1461
Fax:+1 515 266 5453

Eurofins Sample Code: 464-2017-07050162
Sample Description: Stability Study #1283 – Lentein Complete
Client Sample Code: Accelerated - Month 3 - CSPBWL-170213
PO Number: V85R20170044
Client Code: QD0007548

Entry Date: 07/05/2017
Reporting Date: 07/21/2017

Parabel USA Inc.
attn: Valentina Carpio
7898 S. Headwaters Commerce St. Bldg 3
Fellsmere, FL 32948

Parabel USA Inc.
Attn: Ebenezer Ifeduba
14655 101 Street
Fellsmere, Florida 32948

CERTIFICATE OF ANALYSIS

AR-17-QD-105540-01

Test	Result	
QD252 - Protein - Combustion		**Completed: 07/10/2017**
AOAC 990.03; AOAC 992.15		
* Protein	40.61 %	
QD148 - Moisture by Vacuum Oven		**Completed: 07/10/2017**
AOAC 925.09		
* Moisture and Volatiles - Vacuum Oven	4.8 %	
QD172 - pH		**Completed: 07/06/2017**
AOAC 981.12		
pH	6.79	
QQ141 - Tryptophan (AOAC, Most Matrices)		**Completed: 07/10/2017**
AOAC 988.15		
* Tryptophan	0.87 %	
QQ177 - Cystine & Methionine (AOAC, Most Matrices)		**Completed: 07/14/2017**
AOAC 994.12 mod.		
* Cystine	0.43 %	
* Methionine	0.84 %	
QQ176 - Amino Acids by AH (AOAC, Most Matrices)		**Completed: 07/10/2017**
AOAC 982.30 mod.		
* Alanine	2.38 %	
* Arginine	2.62 %	
* Aspartic Acid	3.80 %	
* Glutamic Acid	4.38 %	
* Glycine	2.21 %	
* Histidine	0.91 %	
* Isoleucine	1.99 %	
* Leucine	3.72 %	
* Phenylalanine	2.30 %	
* Proline	1.85 %	
* Serine	1.95 %	
* Threonine	1.89 %	
* Total Lysine	2.78 %	
* Tyrosine	1.44 %	
* Valine	2.49 %	
QD07G - Peroxide Value with Extraction (AOCS)		**Completed: 07/06/2017**
AOCS Cd 8-53		
* Peroxide value	4.0 meq/kg fat	

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AR-17-QD-105540-01

Eurofins Sample Code: 464-2017-07050162
Client Sample Code: Accelerated - Month 3 - CSPBWL-170213

Test	Result	
QD00T - Visual Appearance- Other		**Completed: 07/07/2017**
Internal Method		
Appearance	-	
Fine, vibrant green powder containing smaller, darker green flecks. Prominent grassy aroma. No off-odors.		
QD089 - Fatty Acids-Omega 6 & 3 %W/W		**Completed: 07/11/2017**
AOCS Ce 2-66 AOCS Ce 1-62		
* Fatty Acid Profile, % Weight	Reported as Fatty Acids	
* C08:0 Octanoic (Caprylic)	<0.01 %	
* C10:0 Decanoic (Capric)	<0.01 %	
* C11:0 Undecanoic (Hendecanoic)	<0.01 %	
* C12:0 Dodecanoic (Lauric)	<0.01 %	
* C14:0 Tetradecanoic (Myristic)	0.04 %	
* C14:1 Tetradecenoic (Myristoleic)	<0.01 %	
* C15:0 Pentadecanoic	0.05 %	
* C15:1 Pentadecenoic	<0.01 %	
* C16:0 Hexadecanoic (Palmitic)	1.44 %	
* C16:1 Hexadecenoic (Palmitoleic)	0.31 %	
* C16:2 Hexadecadienoic	<0.01 %	
* C16:3 Hexadecatrienoic	<0.01 %	
* C16:4 Hexadecatetraenoic	<0.01 %	
* C17:0 Heptadecanoic (Margaric)	0.02 %	
* C17:1 Heptadecenoic (Margaroleic)	0.02 %	
* C18:0 Octadecanoic (Stearic)	0.07 %	
* C18:1 Octadecenoic (Oleic)	0.18 %	
* C18:2 Octadecadienoic (Linoleic)	1.32 %	
* C18:2 Octadecadienoic Omega 6	1.28 %	
* C18:3 Octadecatrienoic (Linolenic)	3.37 %	
* C18:3 Octadecatrienoic Omega 3	3.27 %	
* C18:3 Octadecatrienoic Omega 6	0.10 %	
* C18:4 Octadecatetraenoic	0.27 %	
* C18:4 Octadecatetraenoic Omega 3	0.27 %	
* C20:0 Eicosanoic (Arachidic)	0.03 %	
* C20:1 Eicosenoic (Gondoic)	0.03 %	
* C20:2 Eicosadienoic	0.01 %	
* C20:2 Eicosadienoic Omega 6	0.01 %	
* C20:3 Eicosatrienoic	0.02 %	
* C20:3 Eicosatrienoic Omega 3	0.02 %	
* C20:3 Eicosatrienoic Omega 6	<0.01 %	
* C20:4 Eicosatetraenoic (Arachidonic)	0.01 %	
* C20:4 Eicosatetraenoic Omega 3	<0.01 %	
* C20:4 Eicosatetraenoic Omega 6	<0.01 %	
* C20:5 Eicosapentaenoic	0.01 %	
* C20:5 Eicosapentaenoic Omega 3	0.01 %	
* C21:5 Heneicosapentaenoic	<0.01 %	
* C21:5 Heneicosapentaenoic Omega 3	<0.01 %	
* C22:0 Docosanoic (Behenic)	0.04 %	
* C22:1 Docosenoic (Erucic)	<0.01 %	
* C22:2 Docosadienoic	<0.01 %	
* C22:2 Docosadienoic Omega 6	<0.01 %	
* C22:3 Docosatrienoic	<0.01 %	
* C22:3 Docosatrienoic, Omega 3	<0.01 %	
* C22:4 Docosatetraenoic	<0.01 %	
* C22:4 Docosatetraenoic Omega 6	<0.01 %	
* C22:5 Docosapentaenoic	<0.01 %	
* C22:5 Docosapentaenoic Omega 3	<0.01 %	

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AR-17-QD-105540-01

Eurofins Sample Code: 464-2017-07050162
Client Sample Code: Accelerated - Month 3 - CSPBWL-170213

Test	Result	
QD089 - Fatty Acids-Omega 6 & 3 %W/W (Cont.)		**Completed: 07/11/2017**
AOCS Ce 2-66 AOCS Ce 1-62		
* C22:5 Docosapentaenoic Omega 6	<0.01 %	
* C22:6 Docosahexaenoic	<0.01 %	
* C22:6 Docosahexaenoic Omega 3	<0.01 %	
* C24:0 Tetracosanoic (Lignoceric)	0.10 %	
* C24:1 Tetracosenoic (Nervonic)	<0.01 %	
* Sum of Omega 3 Isomers	3.57 %	
* Sum of Omega 6 Isomers	1.40 %	
* Total Fatty Acids Calc.	7.35 %	
UM7MY - Total Aerobic Microbial Count - USP Chapter <61>		**Completed: 07/11/2017**
U.S. Pharmacopeia Chapter 61		
Total Aerobic Microbial Count	42,000 cfu/g	
UMR5L - Moulds - USP Chapter <61>		**Completed: 07/11/2017**
U.S. Pharmacopeia Chapter 61		
Mold	< 10 cfu/g	
Yeast	< 10 cfu/g	
Yeast & Moulds	< 10 cfu/g	
QQ167 - Water Activity		**Completed: 07/07/2017**
AOAC 978.18		
* Water Activity at 25°C	0.159	
SK06I - Hexanal and Propanal		**Completed: 07/20/2017**
No Reference		
Hexanal	2.8 mg/kg	
Propanal	3.4 mg/kg	

**The test result is covered by our current A2LA accreditation.*

Respectfully Submitted,
Eurofins Scientific Inc.

(b) (6)

David Gross
Support Services Manager

A2LA ACCREDITED Biological Testing Cert:3329:01

A2LA ACCREDITED Chemical Testing Cert:2927:01

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Eurofins Scientific Inc.
Nutrition Analysis Center
2200 Rittenhouse Street, Suite 150
Des Moines, IA 50321
Tel:+1 515 265 1461
Fax:+1 515 266 5453

Eurofins Sample Code: 464-2017-07050163
Sample Description: Stability Study #1284 – Lentein Complete
Client Sample Code: Accelerated - Month 3 - CSPBWL-170310
PO Number: V85R20170044
Client Code: QD0007548

Entry Date: 07/05/2017
Reporting Date: 07/21/2017

Parabel USA Inc.
attn: Valentina Carpio
7898 S. Headwaters Commerce St. Bldg 3
Fellsmere, FL 32948

Parabel USA Inc.
Attn: Ebenezer Ifeduba
14655 101 Street
Fellsmere, Florida 32948

CERTIFICATE OF ANALYSIS

AR-17-QD-105541-01

Test	Result	
QD252 - Protein - Combustion		**Completed: 07/10/2017**
AOAC 990.03; AOAC 992.15		
* Protein	42.84 %	
QD148 - Moisture by Vacuum Oven		**Completed: 07/10/2017**
AOAC 925.09		
* Moisture and Volatiles - Vacuum Oven	1.3 %	
QD172 - pH		**Completed: 07/06/2017**
AOAC 981.12		
pH	6.81	
QQ141 - Tryptophan (AOAC, Most Matrices)		**Completed: 07/10/2017**
AOAC 988.15		
* Tryptophan	0.90 %	
QQ177 - Cystine & Methionine (AOAC, Most Matrices)		**Completed: 07/14/2017**
AOAC 994.12 mod.		
* Cystine	0.46 %	
* Methionine	0.91 %	
QQ176 - Amino Acids by AH (AOAC, Most Matrices)		**Completed: 07/10/2017**
AOAC 982.30 mod.		
* Alanine	2.52 %	
* Arginine	2.78 %	
* Aspartic Acid	4.02 %	
* Glutamic Acid	4.68 %	
* Glycine	2.34 %	
* Histidine	0.97 %	
* Isoleucine	2.15 %	
* Leucine	3.94 %	
* Phenylalanine	2.46 %	
* Proline	1.98 %	
* Serine	2.01 %	
* Threonine	1.99 %	
* Total Lysine	3.01 %	
* Tyrosine	1.53 %	
* Valine	2.66 %	
QD07G - Peroxide Value with Extraction (AOCS)		**Completed: 07/06/2017**
AOCS Cd 8-53		
* Peroxide value	4.0 meq/kg fat	

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AR-17-QD-105541-01

Eurofins Sample Code: 464-2017-07050163
Client Sample Code: Accelerated - Month 3 - CSPBWL-170310

Test	Result	
QD00T - Visual Appearance- Other		**Completed: 07/07/2017**
Internal Method		
Appearance	-	
Fine, vibrant green powder containing smaller, darker green flecks. Prominent grassy aroma. No off-odors.		
QD089 - Fatty Acids-Omega 6 & 3 %W/W		**Completed: 07/11/2017**
AOCS Ce 2-66 AOCS Ce 1-62		
* Fatty Acid Profile, % Weight	Reported as Fatty Acids	
* C08:0 Octanoic (Caprylic)	<0.01 %	
* C10:0 Decanoic (Capric)	<0.01 %	
* C11:0 Undecanoic (Hendecanoic)	<0.01 %	
* C12:0 Dodecanoic (Lauric)	<0.01 %	
* C14:0 Tetradecanoic (Myristic)	0.04 %	
* C14:1 Tetradecenoic (Myristoleic)	<0.01 %	
* C15:0 Pentadecanoic	0.06 %	
* C15:1 Pentadecenoic	<0.01 %	
* C16:0 Hexadecanoic (Palmitic)	1.71 %	
* C16:1 Hexadecenoic (Palmitoleic)	0.34 %	
* C16:2 Hexadecadienoic	<0.01 %	
* C16:3 Hexadecatrienoic	<0.01 %	
* C16:4 Hexadecatetraenoic	<0.01 %	
* C17:0 Heptadecanoic (Margaric)	0.02 %	
* C17:1 Heptadecenoic (Margaroleic)	0.02 %	
* C18:0 Octadecanoic (Stearic)	0.08 %	
* C18:1 Octadecenoic (Oleic)	0.22 %	
* C18:2 Octadecadienoic (Linoleic)	1.46 %	
* C18:2 Octadecadienoic Omega 6	1.43 %	
* C18:3 Octadecatrienoic (Linolenic)	4.26 %	
* C18:3 Octadecatrienoic Omega 3	4.15 %	
* C18:3 Octadecatrienoic Omega 6	0.11 %	
* C18:4 Octadecatetraenoic	0.33 %	
* C18:4 Octadecatetraenoic Omega 3	0.33 %	
* C20:0 Eicosanoic (Arachidic)	0.02 %	
* C20:1 Eicosenoic (Gondoic)	0.03 %	
* C20:2 Eicosadienoic	0.01 %	
* C20:2 Eicosadienoic Omega 6	0.01 %	
* C20:3 Eicosatrienoic	0.02 %	
* C20:3 Eicosatrienoic Omega 3	0.02 %	
* C20:3 Eicosatrienoic Omega 6	<0.01 %	
* C20:4 Eicosatetraenoic (Arachidonic)	<0.01 %	
* C20:4 Eicosatetraenoic Omega 3	<0.01 %	
* C20:4 Eicosatetraenoic Omega 6	<0.01 %	
* C20:5 Eicosapentaenoic	<0.01 %	
* C20:5 Eicosapentaenoic Omega 3	<0.01 %	
* C21:5 Heneicosapentaenoic	<0.01 %	
* C21:5 Heneicosapentaenoic Omega 3	<0.01 %	
* C22:0 Docosanoic (Behenic)	0.04 %	
* C22:1 Docosenoic (Erucic)	<0.01 %	
* C22:2 Docosadienoic	<0.01 %	
* C22:2 Docosadienoic Omega 6	<0.01 %	
* C22:3 Docosatrienoic	<0.01 %	
* C22:3 Docosatrienoic, Omega 3	<0.01 %	
* C22:4 Docosatetraenoic	<0.01 %	
* C22:4 Docosatetraenoic Omega 6	<0.01 %	
* C22:5 Docosapentaenoic	<0.01 %	
* C22:5 Docosapentaenoic Omega 3	<0.01 %	

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AR-17-QD-105541-01

Eurofins Sample Code: 464-2017-07050163
Client Sample Code: Accelerated - Month 3 - CSPBWL-170310

Test	Result	
QD089 - Fatty Acids-Omega 6 & 3 %W/W (Cont.)		**Completed: 07/11/2017**
AOCS Ce 2-66 AOCS Ce 1-62		
* C22:5 Docosapentaenoic Omega 6	<0.01 %	
* C22:6 Docosahexaenoic	<0.01 %	
* C22:6 Docosahexaenoic Omega 3	<0.01 %	
* C24:0 Tetracosanoic (Lignoceric)	0.10 %	
* C24:1 Tetracosenoic (Nervonic)	<0.01 %	
* Sum of Omega 3 Isomers	4.50 %	
* Sum of Omega 6 Isomers	1.56 %	
* Total Fatty Acids Calc.	8.78 %	
UM7MY - Total Aerobic Microbial Count - USP Chapter <61>		**Completed: 07/11/2017**
U.S. Pharmacopeia Chapter 61		
Total Aerobic Microbial Count	140,000 cfu/g	
UMR5L - Moulds - USP Chapter <61>		**Completed: 07/11/2017**
U.S. Pharmacopeia Chapter 61		
Mold	< 10 cfu/g	
Yeast	85 (est) cfu/g	
Yeast & Moulds	85 (est) cfu/g	
QQ167 - Water Activity		**Completed: 07/07/2017**
AOAC 978.18		
* Water Activity at 25°C	0.041	
SK06I - Hexanal and Propanal		**Completed: 07/20/2017**
No Reference		
Hexanal	1.5 mg/kg	
Propanal	2.1 mg/kg	

**The test result is covered by our current A2LA accreditation.*

Respectfully Submitted,
Eurofins Scientific Inc.

(b) (6)

David Gross
Support Services Manager

Biological Testing
Cert:3329:01

Chemical Testing
Cert:2927:01

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eurofins | Nutrition Analysis Center

Eurofins Scientific Inc.
Nutrition Analysis Center
2200 Rittenhouse Street, Suite 150
Des Moines, IA 50321
Tel:+1 515 265 1461
Fax:+1 515 266 5453

Eurofins Sample Code: 464-2017-08080178
Sample Description: Stability Study #1282 – Lentein Complete
Client Sample Code: Accelerated -Month 3 - CSPBWL-170308
PO Number: Stability Study #1282
Client Code: QD0007548

Entry Date: 08/08/2017
Reporting Date: 08/18/2017

Parabel USA Inc.
attn: Valentina Carpio
7898 S. Headwaters Commerce St. Bldg 3
Fellsmere, FL 32948

Parabel USA Inc.
Attn: Ebenezer Ifeduba
14655 101 Street
Fellsmere, Florida 32948

CERTIFICATE OF ANALYSIS

AR-17-QD-121375-01

Test	Result	
QD252 - Protein - Combustion		**Completed: 08/11/2017**
AOAC 990.03; AOAC 992.15		
* Protein	45.24 %	
QD148 - Moisture by Vacuum Oven		**Completed: 08/11/2017**
AOAC 925.09		
* Moisture and Volatiles - Vacuum Oven	1.8 %	
QD172 - pH		**Completed: 08/11/2017**
AOAC 981.12		
pH	6.72	
QQ141 - Tryptophan (AOAC, Most Matrices)		**Completed: 08/14/2017**
AOAC 988.15		
* Tryptophan	0.99 %	
QQ177 - Cystine & Methionine (AOAC, Most Matrices)		**Completed: 08/14/2017**
AOAC 994.12 mod.		
* Cystine	0.45 %	
* Methionine	0.98 %	
QQ176 - Amino Acids by AH (AOAC, Most Matrices)		**Completed: 08/15/2017**
AOAC 982.30 mod.		
* Alanine	2.64 %	
* Arginine	2.88 %	
* Aspartic Acid	4.22 %	
* Glutamic Acid	4.90 %	
* Glycine	2.46 %	
* Histidine	1.01 %	
* Isoleucine	2.25 %	
* Leucine	4.11 %	
* Phenylalanine	2.56 %	
* Proline	2.03 %	
* Serine	2.07 %	
* Threonine	2.08 %	
* Total Lysine	3.12 %	
* Tyrosine	1.67 %	
* Valine	2.81 %	
QD07G - Peroxide Value with Extraction (AOCS)		**Completed: 08/11/2017**
AOCS Cd 8-53		
* Peroxide value	46 meq/kg fat	

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AR-17-QD-121375-01

Eurofins Sample Code: 464-2017-08080178
Client Sample Code: Accelerated -Month 3 - CSPBWL-170308

Test	Result	
QD00T - Visual Appearance- Other		**Completed: 08/10/2017**
Internal Method		
Appearance	-	
Fine, darker green powder containing smaller, lighter green flecks. Slight grassy aroma. No off-odors.		
QD089 - Fatty Acids-Omega 6 & 3 %W/W		**Completed: 08/14/2017**
AOCS Ce 2-66 AOCS Ce 1-62		
* Fatty Acid Profile, % Weight	Reported as Fatty Acids	
* C08:0 Octanoic (Caprylic)	<0.01 %	
* C10:0 Decanoic (Capric)	<0.01 %	
* C11:0 Undecanoic (Hendecanoic)	<0.01 %	
* C12:0 Dodecanoic (Lauric)	<0.01 %	
* C14:0 Tetradecanoic (Myristic)	0.04 %	
* C14:1 Tetradecenoic (Myristoleic)	<0.01 %	
* C15:0 Pentadecanoic	0.06 %	
* C15:1 Pentadecenoic	<0.01 %	
* C16:0 Hexadecanoic (Palmitic)	1.31 %	
* C16:1 Hexadecenoic (Palmitoleic)	0.21 %	
* C16:2 Hexadecadienoic	<0.01 %	
* C16:3 Hexadecatrienoic	<0.01 %	
* C16:4 Hexadecatetraenoic	<0.01 %	
* C17:0 Heptadecanoic (Margaric)	0.02 %	
* C17:1 Heptadecenoic (Margaroleic)	0.01 %	
* C18:0 Octadecanoic (Stearic)	0.07 %	
* C18:1 Octadecenoic (Oleic + isomers)	0.18 %	
* C18:2 Octadecadienoic (Linoleic + isomers)	1.19 %	
* C18:2 Octadecadienoic Omega 6 (Linoleic)	1.17 %	
* C18:3 Octadecatrienoic (Linolenic + isomers)	3.53 %	
* C18:3 Octadecatrienoic Omega 3 (Alpha Linolenic)	3.44 %	
* C18:3 Octadecatrienoic Omega 6 (Gamma Linolenic)	0.10 %	
* C18:4 Octadecatetraenoic Omega 3 (Stearidonic)	0.25 %	
* C20:0 Eicosanoic (Arachidic)	0.03 %	
* C20:1 Eicosenoic (Gondoic + isomers)	0.03 %	
* C20:2 Eicosadienoic Omega 6	0.01 %	
* C20:3 Eicosatrienoic	0.01 %	
* C20:3 Eicosatrienoic Omega 3	0.01 %	
* C20:3 Eicosatrienoic Omega 6	<0.01 %	
* C20:4 Eicosatetraenoic (Arachidonic + isomers)	<0.01 %	
* C20:4 Eicosatetraenoic Omega 3	<0.01 %	
* C20:4 Eicosatetraenoic Omega 6 (Arachidonic)	<0.01 %	
* C20:5 Eicosapentaenoic Omega 3	<0.01 %	
* C21:5 Heneicosapentaenoic Omega 3	<0.01 %	
* C22:0 Docosanoic (Behenic)	0.05 %	
* C22:1 Docosenoic (Erucic + isomers)	0.02 %	
* C22:2 Docosadienoic Omega 6	<0.01 %	
* C22:3 Docosatrienoic, Omega 3	<0.01 %	
* C22:4 Docosatetraenoic Omega 6	<0.01 %	
* C22:5 Docosapentaenoic	<0.01 %	
* C22:5 Docosapentaenoic Omega 3	<0.01 %	
* C22:5 Docosapentaenoic Omega 6	<0.01 %	
* C22:6 Docosahexaenoic Omega 3	0.02 %	
* C24:0 Tetracosanoic (Lignoceric)	0.10 %	
* C24:1 Tetracosenoic (Nervonic)	<0.01 %	
* Sum of Omega 3 Isomers	3.72 %	
* Sum of Omega 6 Isomers	1.28 %	

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AR-17-QD-121375-01

Eurofins Sample Code: 464-2017-08080178
Client Sample Code: Accelerated -Month 3 - CSPBWL-170308

Test	Result	
QD089 - Fatty Acids-Omega 6 & 3 %W/W (Cont.)		**Completed: 08/14/2017**
AOCS Ce 2-66 AOCS Ce 1-62		
* Total Fatty Acids Calc.	7.15 %	
UM7MY - Total Aerobic Microbial Count - USP Chapter <61>		**Completed: 08/15/2017**
U.S. Pharmacopeia Chapter 61		
Total Aerobic Microbial Count	430 cfu/g	
UMR5L - Moulds - USP Chapter <61>		**Completed: 08/15/2017**
U.S. Pharmacopeia Chapter 61		
Mold	< 10 cfu/g	
Yeast	< 10 cfu/g	
Yeast & Moulds	< 10 cfu/g	
QQ167 - Water Activity		**Completed: 08/09/2017**
AOAC 978.18		
* Water Activity at 25°C	0.050	
SK06I - Hexanal and Propanal		**Completed: 08/18/2017**
No Reference		
Hexanal	3.7 mg/kg	
Propanal	4.4 mg/kg	

**The test result is covered by our current A2LA accreditation.*

Respectfully Submitted,
Eurofins Scientific Inc.

(b) (6)

Brian Gilchrist
Technical Manager

A2LA ACCREDITED Biological Testing Cert:3329:01

A2LA ACCREDITED Chemical Testing Cert:2927:01

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Accelerated Month 6 Results (Time 6) for 2 LENTEIN Complete batches:

eurofins | Nutrition Analysis Center

Eurofins Scientific Inc.
Nutrition Analysis Center
2200 Rittenhouse Street, Suite 150
Des Moines, IA 50321
Tel:+1 515 265 1461
Fax:+1 515 266 5453

Eurofins Sample Code: 464-2017-10040178
Sample Description: Stability Study #1284 – Lentein Complete
Client Sample Code: Accelerated - Month 6 - CSPBWL-170310
PO Number: Stability Study #1283-1284
Client Code: QD0007548

Entry Date: 10/04/2017
Reporting Date: 10/16/2017

Parabel USA Inc.
Attn: Ebenezer Ifeduba
14655 101 Street
Fellsmere, Florida 32948

CERTIFICATE OF ANALYSIS

AR-17-QD-151487-01

Test	Result	
QD252 - Protein - Combustion		**Completed: 10/09/2017**
AOAC 990.03; AOAC 992.15		
* Protein	42.49 %	
QD148 - Moisture by Vacuum Oven		**Completed: 10/06/2017**
AOAC 925.09		
* Moisture and Volatiles - Vacuum Oven	1.3 %	
QD172 - pH		**Completed: 10/06/2017**
AOAC 981.12		
pH	7.05	
QQ141 - Tryptophan (AOAC, Most Matrices)		**Completed: 10/09/2017**
AOAC 988.15		
* Tryptophan	0.98 %	
QQ177 - Cystine & Methionine (AOAC, Most Matrices)		**Completed: 10/11/2017**
AOAC 994.12 mod.		
* Cystine	0.46 %	
* Methionine	0.91 %	
QQ176 - Amino Acids by AH (AOAC, Most Matrices)		**Completed: 10/09/2017**
AOAC 982.30 mod.		
* Alanine	2.71 %	
* Arginine	2.75 %	
* Aspartic Acid	3.94 %	
* Glutamic Acid	4.65 %	
* Glycine	2.34 %	
* Histidine	0.95 %	
* Isoleucine	2.13 %	
* Leucine	3.85 %	
* Phenylalanine	2.37 %	
* Proline	2.05 %	
* Serine	1.99 %	
* Threonine	1.98 %	
* Total Lysine	3.27 %	
* Tyrosine	1.56 %	
* Valine	2.63 %	
QD07G - Peroxide Value with Extraction (AOCS)		**Completed: 10/06/2017**
AOCS Cd 8-53		
* Peroxide value	11 meq/kg fat	

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AR-17-QD-151487-01

Eurofins Sample Code: 464-2017-10040178
Client Sample Code: Accelerated - Month 6 - CSPBWL-170310

Test	Result	
QD00T - Visual Appearance- Other		**Completed: 10/05/2017**
Internal Method		
Appearance	-	
Fine, green powder containing smaller, lighter green flecks. Slight grassy aroma. No off-odors.		
QD089 - Fatty Acids-Omega 6 & 3 %W/W		**Completed: 10/11/2017**
AOCS Ce 2-66 AOCS Ce 1-62		
* Fatty Acid Profile, % Weight	Reported as Fatty Acids	
* C08:0 Octanoic (Caprylic)	<0.01 %	
* C10:0 Decanoic (Capric)	<0.01 %	
* C11:0 Undecanoic (Hendecanoic)	<0.01 %	
* C12:0 Dodecanoic (Lauric)	<0.01 %	
* C14:0 Tetradecanoic (Myristic)	0.04 %	
* C14:1 Tetradecenoic (Myristoleic)	<0.01 %	
* C15:0 Pentadecanoic	0.06 %	
* C15:1 Pentadecenoic	<0.01 %	
* C16:0 Hexadecanoic (Palmitic)	1.63 %	
* C16:1 Hexadecenoic (Palmitoleic)	0.34 %	
* C16:2 Hexadecadienoic	<0.01 %	
* C16:3 Hexadecatrienoic	<0.01 %	
* C16:4 Hexadecatetraenoic	<0.01 %	
* C17:0 Heptadecanoic (Margaric)	0.02 %	
* C17:1 Heptadecenoic (Margaroleic)	0.02 %	
* C18:0 Octadecanoic (Stearic)	0.08 %	
* C18:1 Octadecenoic (Oleic + isomers)	0.21 %	
* C18:2 Octadecadienoic (Linoleic + isomers)	1.35 %	
* C18:2 Octadecadienoic Omega 6 (Linoleic)	1.34 %	
* C18:3 Octadecatrienoic (Linolenic + isomers)	4.08 %	
* C18:3 Octadecatrienoic Omega 3 (Alpha Linolenic)	3.97 %	
* C18:3 Octadecatrienoic Omega 6 (Gamma Linolenic)	0.12 %	
* C18:4 Octadecatetraenoic Omega 3 (Stearidonic)	0.31 %	
* C20:0 Eicosanoic (Arachidic)	0.02 %	
* C20:1 Eicosenoic (Gondoic + isomers)	<0.01 %	
* C20:2 Eicosadienoic Omega 6	<0.01 %	
* C20:3 Eicosatrienoic	0.02 %	
* C20:3 Eicosatrienoic Omega 3	0.02 %	
* C20:3 Eicosatrienoic Omega 6	<0.01 %	
* C20:4 Eicosatetraenoic (Arachidonic + isomers)	<0.01 %	
* C20:4 Eicosatetraenoic Omega 3	<0.01 %	
* C20:4 Eicosatetraenoic Omega 6 (Arachidonic)	<0.01 %	
* C20:5 Eicosapentaenoic Omega 3	<0.01 %	
* C21:5 Heneicosapentaenoic Omega 3	<0.01 %	
* C22:0 Docosanoic (Behenic)	0.04 %	
* C22:1 Docosenoic (Erucic + isomers)	<0.01 %	
* C22:2 Docosadienoic Omega 6	<0.01 %	
* C22:3 Docosatrienoic, Omega 3	<0.01 %	
* C22:4 Docosatetraenoic Omega 6	<0.01 %	
* C22:5 Docosapentaenoic	<0.01 %	
* C22:5 Docosapentaenoic Omega 3	<0.01 %	
* C22:5 Docosapentaenoic Omega 6	<0.01 %	
* C22:6 Docosahexaenoic Omega 3	<0.01 %	
* C24:0 Tetracosanoic (Lignoceric)	0.10 %	
* C24:1 Tetracosenoic (Nervonic)	<0.01 %	
* Sum of Omega 3 Isomers	4.29 %	
* Sum of Omega 6 Isomers	1.46 %	

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AR-17-QD-151487-01

Eurofins Sample Code: 464-2017-10040178
Client Sample Code: Accelerated - Month 6 - CSPBWL-170310

Test	Result	
QD089 - Fatty Acids-Omega 6 & 3 %W/W (Cont.)		**Completed: 10/11/2017**
AOCS Ce 2-66 AOCS Ce 1-62		
* Total Fatty Acids Calc.	8.32 %	
UM7MY - Total Aerobic Microbial Count - USP Chapter <61>		**Completed: 10/10/2017**
U.S. Pharmacopeia Chapter 61		
Total Aerobic Microbial Count	34,000 cfu/g	
UMR5L - Moulds - USP Chapter <61>		**Completed: 10/10/2017**
U.S. Pharmacopeia Chapter 61		
Mold	< 10 cfu/g	
Yeast	< 10 cfu/g	
Yeast & Moulds	< 10 cfu/g	
QQ167 - Water Activity		**Completed: 10/10/2017**
AOAC 978.18		
* Water Activity at 25°C	0.041	
SK06I - Hexanal and Propanal		**Completed: 10/16/2017**
No Reference		
Hexanal	1.1 mg/kg	
Propanal	3.1 mg/kg	

**The test result is covered by our current A2LA accreditation.*

Respectfully Submitted,
Eurofins Scientific Inc.

(b) (6)

Jennifer Jensen
Manager Scientific

A2LA ACCREDITED Biological Testing Cert:3329:01

A2LA ACCREDITED Chemical Testing Cert:2927:01

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eurofins | Nutrition Analysis Center

Eurofins Scientific Inc.
Nutrition Analysis Center
2200 Rittenhouse Street, Suite 150
Des Moines, IA 50321
Tel:+1 515 265 1461
Fax:+1 515 266 5453

Eurofins Sample Code: 464-2017-10040177
Sample Description: Stability Study #1283 – Lentein Complete
Client Sample Code: Accelerated - Month 6 - CSPBWL-170213
PO Number: Stability Study #1283-1284
Client Code: QD0007548

Entry Date: 10/04/2017
Reporting Date: 10/16/2017

Parabel USA Inc.
Attn: Ebenezer Ifeduba
14655 101 Street
Fellsmere, Florida 32948

CERTIFICATE OF ANALYSIS

AR-17-QD-151486-01

Test	Result	
QD252 - Protein - Combustion		**Completed: 10/09/2017**
AOAC 990.03; AOAC 992.15		
* Protein	40.77 %	
QD148 - Moisture by Vacuum Oven		**Completed: 10/06/2017**
AOAC 925.09		
* Moisture and Volatiles - Vacuum Oven	4.7 %	
QD172 - pH		**Completed: 10/06/2017**
AOAC 981.12		
pH	7.08	
QQ141 - Tryptophan (AOAC, Most Matrices)		**Completed: 10/09/2017**
AOAC 988.15		
* Tryptophan	0.93 %	
QQ177 - Cystine & Methionine (AOAC, Most Matrices)		**Completed: 10/11/2017**
AOAC 994.12 mod.		
* Cystine	0.42 %	
* Methionine	0.87 %	
QQ176 - Amino Acids by AH (AOAC, Most Matrices)		**Completed: 10/09/2017**
AOAC 982.30 mod.		
* Alanine	2.60 %	
* Arginine	2.64 %	
* Aspartic Acid	3.75 %	
* Glutamic Acid	4.39 %	
* Glycine	2.24 %	
* Histidine	0.92 %	
* Isoleucine	2.11 %	
* Leucine	3.70 %	
* Phenylalanine	2.28 %	
* Proline	1.90 %	
* Serine	1.85 %	
* Threonine	1.85 %	
* Total Lysine	2.99 %	
* Tyrosine	1.48 %	
* Valine	2.60 %	
QD07G - Peroxide Value with Extraction (AOCS)		**Completed: 10/06/2017**
AOCS Cd 8-53		
* Peroxide value	10 meq/kg fat	

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AR-17-QD-151486-01

Eurofins Sample Code: 464-2017-10040177
Client Sample Code: Accelerated - Month 6 - CSPBWL-170213

Test	Result
QD00T - Visual Appearance- Other	**Completed: 10/05/2017**
Internal Method	
Appearance	-
Fine, darker green powder containing smaller, lighter green flecks. Slight grassy aroma. No off-odors.	
QD089 - Fatty Acids-Omega 6 & 3 %W/W	**Completed: 10/11/2017**
AOCS Ce 2-66 AOCS Ce 1-62	
* Fatty Acid Profile, % Weight	Reported as Fatty Acids
* C08:0 Octanoic (Caprylic)	<0.01 %
* C10:0 Decanoic (Capric)	<0.01 %
* C11:0 Undecanoic (Hendecanoic)	<0.01 %
* C12:0 Dodecanoic (Lauric)	<0.01 %
* C14:0 Tetradecanoic (Myristic)	0.04 %
* C14:1 Tetradecenoic (Myristoleic)	<0.01 %
* C15:0 Pentadecanoic	0.05 %
* C15:1 Pentadecenoic	<0.01 %
* C16:0 Hexadecanoic (Palmitic)	1.53 %
* C16:1 Hexadecenoic (Palmitoleic)	0.36 %
* C16:2 Hexadecadienoic	<0.01 %
* C16:3 Hexadecatrienoic	<0.01 %
* C16:4 Hexadecatetraenoic	<0.01 %
* C17:0 Heptadecanoic (Margaric)	0.02 %
* C17:1 Heptadecenoic (Margaroleic)	0.01 %
* C18:0 Octadecanoic (Stearic)	0.08 %
* C18:1 Octadecenoic (Oleic + isomers)	0.17 %
* C18:2 Octadecadienoic (Linoleic + isomers)	1.31 %
* C18:2 Octadecadienoic Omega 6 (Linoleic)	1.30 %
* C18:3 Octadecatrienoic (Linolenic + isomers)	3.50 %
* C18:3 Octadecatrienoic Omega 3 (Alpha Linolenic)	3.40 %
* C18:3 Octadecatrienoic Omega 6 (Gamma Linolenic)	0.10 %
* C18:4 Octadecatetraenoic Omega 3 (Stearidonic)	0.29 %
* C20:0 Eicosanoic (Arachidic)	0.03 %
* C20:1 Eicosenoic (Gondoic + isomers)	<0.01 %
* C20:2 Eicosadienoic Omega 6	<0.01 %
* C20:3 Eicosatrienoic	<0.01 %
* C20:3 Eicosatrienoic Omega 3	<0.01 %
* C20:3 Eicosatrienoic Omega 6	<0.01 %
* C20:4 Eicosatetraenoic (Arachidonic + isomers)	<0.01 %
* C20:4 Eicosatetraenoic Omega 3	<0.01 %
* C20:4 Eicosatetraenoic Omega 6 (Arachidonic)	<0.01 %
* C20:5 Eicosapentaenoic Omega 3	<0.01 %
* C21:5 Heneicosapentaenoic Omega 3	<0.01 %
* C22:0 Docosanoic (Behenic)	0.04 %
* C22:1 Docosenoic (Erucic + isomers)	<0.01 %
* C22:2 Docosadienoic Omega 6	<0.01 %
* C22:3 Docosatrienoic, Omega 3	<0.01 %
* C22:4 Docosatetraenoic Omega 6	<0.01 %
* C22:5 Docosapentaenoic	<0.01 %
* C22:5 Docosapentaenoic Omega 3	<0.01 %
* C22:5 Docosapentaenoic Omega 6	<0.01 %
* C22:6 Docosahexaenoic Omega 3	<0.01 %
* C24:0 Tetracosanoic (Lignoceric)	0.08 %
* C24:1 Tetracosenoic (Nervonic)	<0.01 %
* Sum of Omega 3 Isomers	3.69 %
* Sum of Omega 6 Isomers	1.40 %

eurofins

AR-17-QD-151486-01

Eurofins Sample Code: 464-2017-10040177
Client Sample Code: Accelerated - Month 6 - CSPBWL-170213

Test	Result	
QD089 - Fatty Acids-Omega 6 & 3 %W/W (Cont.)		**Completed: 10/11/2017**
AOCS Ce 2-66 AOCS Ce 1-62		
* Total Fatty Acids Calc.	7.53 %	
UM7MY - Total Aerobic Microbial Count - USP Chapter <61>		**Completed: 10/10/2017**
U.S. Pharmacopeia Chapter 61		
Total Aerobic Microbial Count	8,900 cfu/g	
UMR5L - Moulds - USP Chapter <61>		**Completed: 10/10/2017**
U.S. Pharmacopeia Chapter 61		
Mold	10 (est) cfu/g	
Yeast	< 10 cfu/g	
Yeast & Moulds	10 (est) cfu/g	
QQ167 - Water Activity		**Completed: 10/10/2017**
AOAC 978.18		
* Water Activity at 25°C	0.183	
SK06I - Hexanal and Propanal		**Completed: 10/16/2017**
No Reference		
Hexanal	1.2 mg/kg	
Propanal	1.1 mg/kg	

**The test result is covered by our current A2LA accreditation.*

Respectfully Submitted,
Eurofins Scientific Inc.

(b) (6)

Jennifer Jensen
Manager Scientific

ACCREDITED Biological Testing Cert:3329:01

ACCREDITED Chemical Testing Cert:2927:01

Results shown in this report relate solely to the item submitted for analysis.
All results are reported on an "As Received" basis unless otherwise stated.
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Eurofins Scientific, Inc. Measurement of Uncertainty can be obtained upon request.

Appendix G: LPC Specification Sheet

Parabel
PO Box 113561, Abu Dhabi, UAE
Tel. +971 2644 3800
www.parabel.com

LEMNA PROTEIN CONCENTRATE

FEED INGREDIENT

Plant protein concentrate powder produced from non-GMO *Lemnoideae* aquatic plants

TYPICAL COMPOSITION	As-fed %
Moisture	Max. 12
Crude protein	Min. 57
Ash	Max. 15
Fat, acid hydrolysis	10
Neutral detergent fiber	2
Starch	1
Sugar	1

MINERALS	As-fed
Potassium	2.8%
Phosphorus, total	1.4%
Phosp., non-phytate	1.3%
Sodium	0.6%
Magnesium	0.5%
Calcium	0.4%
Iron	1000 ppm
Manganese	438 ppm
Zinc	123 ppm
Copper	32 ppm
Cobalt	0.8 ppm
Selenium	0.3 ppm

AMINO ACIDS	As-fed %	Digestible[1] %
Arginine	3.4	2.8
Histidine	1.2	1.0
Isoleucine	2.6	2.1
Leucine	4.7	3.8
Lysine	3.3	2.9
Methionine	1.0	0.9
Phenylalanine	2.9	2.5
Threonine	2.9	2.4
Tryptophan	1.2	NA
Valine	3.4	2.8

VITAMINS, PIGMENTS	As-fed per kg
Vitamin A (β-carotene)	414,000 IU
Vitamin E (α-tocopherol)	122 IU
Lutein	621 mg
Zeaxanthin	28 mg

[1]Apparent digestibility coefficients observed in Pacific white shrimp

Lemna Protein Concentrate is a natural product and its composition may vary

This information is non-binding and is provided for informative purposes only
Rev. 2015/04

Appendix H: Safe Levels of Trace Elements in Food

November 25, 2013

Several expert bodies have reviewed the hazards of trace elements that may contaminate food. The US Agency for Toxic Substances and Disease Registry (ATSDR) has published Toxicology Profiles of the hazardous substances commonly found at hazardous waste sites. ATSDR includes any known information about background levels of these substances in food in the Toxicology Profiles. In the UK, The Committee on Toxicity of Chemicals in Food, Consumer Products, and the Environment (COT) has evaluated the safety of trace elements present in food (COT, 2008). The COT reviews exposure levels estimated in the 2006 UK Total Diet Study, which is based on composite samples for 20 food groups collected from 24 UK towns, and analyzed for their levels of 25 trace elements. The results from this survey have been used to estimate dietary exposure to these elements for UK consumers and provide up-to-date information on their concentrations in foods. The World Health Organization (WHO) has published opinions on safe oral exposures to various trace elements in their guidelines for drinking water quality (WHO, 2011). In addition, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has reviewed safe levels of various trace elements in food. Safe doses, expressed in units of mg/kg body weight (bw), have been converted to mg/person/day based on the assumption of adult weight of 60 kg.

Aluminum

In the UK in 2009, the dietary exposure to aluminum was estimated at 5.4 mg/day. The mean level consumers of all the population groups had intakes within the Provisional Tolerable Weekly Intake (PTWI) of 1 mg/kg bw equivalent to a daily exposure of 143 µg/kg bw) that was set by JECFA in 2006. This value was also reported in the WHO Guidelines for Drinking Water Quality (WHO, 2011). The COT found that the estimates of high-level dietary exposure of toddlers, young people, the elderly, and vegetarians exceeded the PTWI by up to 2.4 fold. In the US, the ATSDR reported that an average adult obtains about 7-9 mg of aluminum per day in their food (ATSDR, 2008). ATSDR cites other sources of oral exposure to aluminum compounds, such as drinking water, antacids, and buffered aspirin.

2. Arsenic (total)

In the 2006 UK Total Diet Study, the population dietary exposure to total arsenic was estimated to be 0.061-0.064 mg/day. The COT concluded that current dietary exposure to organic arsenic is unlikely to constitute a risk to health (UK, 2009). In the US, the ATSDR reported that the total amount of arsenic consumed from food sources is generally about 50 µg each day (ATSDR, 2007a). In the WHO Guidelines for Drinking Water Quality, it was reported that a JECFA PTWI of 15 µg arsenic/kg bw was recently withdrawn because the PTWI was very close to the lower confidence limit on the benchmark dose for a 0.5% response ($BMDL_{0.5}$) (WHO, 2011). However, WHO notes that in many countries, the PTWI of 15 µg arsenic/kg bw is retained, given water treatment capabilities and analytical

methodology limits, and that all "effort[s] should be made to keep concentrations as low as reasonably possible" (WHO, 2011).

3. Boron

Boron was not one of the elements analyzed in the 2006 UK Total Diet Study. ATSDR reported that the average dietary daily intake of boron for adults is 1 mg (ATSDR, 2010). The WHO Guidelines for Drinking Water reported a TDI of 0.17 mg/kg body weight, based on a $BMDL_{0.5}$ of 10.3 mg/kg bw/day for developmental toxicity (decreased fetal body weight in rats) and an uncertainty factor of 60 (10 for interspecies variation and 6 for intraspecies variation) (WHO, 2011). The Expert Group on Vitamins and Minerals determined the safe upper level for daily consumption of boron over a lifetime at 0.16 mg boron/kg bw/day (2003).

4. Calcium

Calcium was not reviewed by ATSDR or WHO, or reported in the UK study because it is not considered hazardous. Calcium is considered Generally Recognized as Safe (GRAS) in food in the US. Several calcium salts are listed as GRAS for use in food in 21 CFR Part 184. There are insufficient data available on the safe upper level for calcium (Expert Group on Vitamins and Minerals, 2003).

5. Chromium

In the 2006 UK Total Diet Study, the reported population dietary exposure to chromium was 0.029 mg/day. The COT concluded that current dietary exposures to chromium are of no toxicological concern (UK, 2009). ATSDR reports that the general population is most likely to be exposed to trace levels of chromium in the diet (ATSDR, 2012a). The WHO Guidelines for Drinking Water Quality reported a trace chromium concentration in drinking water of usually less than 2 µg/L, although concentrations as high as 120 µg/L have been reported (WHO, 2011). There are insufficient data available to determine the safe upper level for chromium (Expert Group on Vitamins and Minerals, 2003).

6. Cobalt

Cobalt was not one of the elements reported in the 2006 UK Total Dietary Study. In the US, ATSDR reported that the average person consumes 11 µg of cobalt a day in the diet (ATSDR, 2004a). Cobalt was not discussed in the WHO Guidelines for Drinking Water Quality. There are insufficient data available to determine the safe upper level for cobalt (Expert Group on Vitamins and Minerals, 2003).

7. Copper

In the 2006 UK Total Diet Study, the reported population dietary exposure to copper was 1.24 mg/day. The COT concluded that current dietary exposures to copper are not of

toxicological concern (UK, 2009). In the US, ATSDR reported that the average person consumes 1 mg of copper per day (ATSDR, 2004b). In the WHO Guidelines for Drinking Water Quality, it was reported that the upper limit of the acceptable range of oral intake in adults is uncertain, but is most likely in the range of several mg/day in adults (WHO, 2011). The Expert Group on Vitamins and Minerals determined the safe upper level for daily consumption of boron over a lifetime at 0.16 mg copper/kg bw/day (2003). Gastrointestinal distress has been observed with copper intake of 5 mg/d (Omaye, 2004).

8. Iodine

Iodine was not one of the elements reported in the 2006 UK Total Dietary Study. In 2001, the Institute of Medicine reported an upper limit of 1,100 µg per day (IOM, 2001). In the WHO Guidelines for Drinking Water Quality, it was reported that the available data is inadequate to determine a health-based guideline value (WHO, 2011). No US dietary exposure estimates were provided by ATSDR; however, the National Research Council established a Recommended Dietary Allowance (RDA) for iodine of 150 µg/day (ATSDR, 2004d). There are insufficient data available to determine the safe upper level for cobalt (Expert Group on Vitamins and Minerals, 2003).

9. Iron

Iron was not one of the elements reported in the 2006 UK Total Dietary Study. The Institute of Medicine (IOM) reported an upper limit of 45 mg/day (IOM, 2001). In the WHO Guidelines for Drinking Water Quality, it was reported that, in 1983, JECFA established a PMTDI of 0.8 mg/kg bw (WHO, 2011). Several salts of iron are listed as GRAS for use in food in the US in 21 CFR Part 184. ATSDR has not prepared a Toxicological Profile for iron. There are insufficient data available to determine the safe upper level for cobalt (Expert Group on Vitamins and Minerals, 2003).

10. Lead

It was reported in the 2006 UK Total Diet Study that the population dietary exposure to lead is 0.006 mg/day. The COT concluded that, at this dietary intake, the likelihood of adverse effects is small (UK, 2009). In the US, it is reported that the average dietary intake is about 1 µg/day (ATSDR, 2007b). In the WHO Guidelines for Drinking Water Quality, it was reported that JECFA withdrew a PTWI of 25 µg/kg bw because it was no longer considered to be health-protective. A new PTWI has not been established (WHO, 2011).

11. Magnesium

Magnesium was not reviewed by ATSDR or WHO, or reported in the UK study because it is not considered to be hazardous. Magnesium is Generally Recognized as Safe (GRAS) in food in the US. Several salts of magnesium are listed as GRAS for use in food in 21 CFR Part 184. There are insufficient data available to determine the safe upper level for magnesium (Expert Group on Vitamins and Minerals, 2003).

12. Manganese

In the 2006 UK Total Diet Study, it was reported that the general population consumes up to 200 µg manganese/kg bw/day. The COT concluded that there is insufficient information to determine whether there are risks associated with dietary exposure to manganese. However, the dietary exposures to manganese in adults have remained fairly constant since 1983, and there is no basis for assuming any concern for health (UK, 2009). In the US, the average adult intake for manganese ranges from 0.7 to 10.9 mg/day (ATSDR, 2012a). The upper range of 11 mg/day for manganese from dietary studies is considered a no-observed-adverse effect level (NOAEL). Using this upper range value, a health-based value can be calculated. Using an uncertainty factor of 3 and an adult body weight of 60 kg, a tolerable daily intake of 0.06 mg/kg bw can be calculated based on a NOAEL of 11 mg/day (WHO, 2011). In addition, several salts of manganese are listed as GRAS for use in food in the US in 21 CFR Part 184. Insufficient data exist to determine a safe upper level for manganese (Expert Group on Vitamins and Minerals, 2003).

13. Mercury

According to the 2006 UK Total Diet Study, the population exposure to mercury is 0.001-0.003 mg/day. The mean adult dietary exposure to mercury is 0.05 mg/kg bw/day. The COT concluded that this current dietary exposure to mercury is unlikely to be of toxicological concern (UK, 2009). JECFA has established a PTWI for methylmercury of 0.33 µg/kg bw/day for the general population (WHO, 2003). In the WHO Guidelines for Drinking Water Quality, it was reported that a TDI of 2 µg/kg body weight (0.12 mg/person/day) for inorganic mercury has been established (WHO, 2011). In the US, The FDA estimates an average dietary exposure level of 50 ng mercury/kg bw/day (ATSDR, 1999).

14. Molybdenum

In the 2006 UK Total Diet Study, it was reported that the general population consumes about 0.123-0.125 mg molybdenum/day. The COT concluded that the sparse data on the oral toxicity of molybdenum do not suggest that these estimated intakes give cause for toxicological concern. According to the WHO Guidelines for Drinking Water Quality, molybdenum occurs in drinking water at concentrations well below those of health concern; however, molybdenum is considered to be an essential element, with an estimated daily requirement of 0.1-0.3 mg for adults (WHO, 2011). ATSDR has not prepared a Toxicological Profile for molybdenum. There are insufficient data available to determine the safe upper level for molybdenum (Expert Group on Vitamins and Minerals, 2003).

15. Nickel

In the 2006 UK Total Diet Study, the population dietary exposure to nickel was estimated to be 0.13 mg/day. The COT concluded that this exposure to nickel was unlikely to be of

toxicological concern (UK, 2009). ATSDR reported that in the US, humans consume about 170 µg nickel from food sources every day (ATSDR, 2005a). The WHO Guidelines for Drinking Water Quality reported a TDI of 12 µg nickel /kg bw (0.7 mg/person/day; WHO, 2011). The total nickel intake of 0.0043 mg/kg bw/day would not be expected to have effects in non-sensitized individuals (Expert Group on Vitamins and Minerals, 2003).

16. Potassium

Potassium was not one of the elements evaluated in the 2006 UK Total Diet Study. In the US, potassium is GRAS. In the WHO Guidelines for Drinking Water Quality, it was reported that potassium is an essential element for humans and the recommended daily requirement is greater than 3000 mg (WHO, 2011). Several salts of potassium are listed as GRAS for use in food in the US in 21 CFR Part 184. There are insufficient data available to determine the safe upper level for potassium (Expert Group on Vitamins and Minerals, 2003). No adverse effects of potassium chloride supplementation were found at daily doses of 1,900 mg (Siani et al. 1991) or 2340 mg (Fotherby and Potter 1992).

17. Selenium

The reported population exposure to selenium in the 2006 UK Total Diet study was 0.048-0.058 mg/day. The COT concluded that this exposure was not of toxicological concern (UK, 2009). ATSDR estimates that the average intake of selenium from food for the US population ranges from 71-152 µg/day (ATSDR, 2003). According to the WHO Guidelines for Drinking Water Quality, selenium is an essential element. JECFA recommends intakes of 6-21 µg selenium/day for infants and children, 26 and 30 µg selenium/day for adolescent females and males, respectively, and 26 and 35 µg selenium/day for adult females and males, respectively. Due to concerns about the adverse effects from over-exposure to selenium, FAO/WHO established an upper limit for selenium of 400 µg/day (WHO, 2011). The safe upper level for daily consumption of selenium over a lifetime was determined to be 0.45 mg total selenium per day (Expert Group on Vitamins and Minerals, 2003). Long-term dietary intake of selenium at 4 to 5 mg/kg can cause growth inhibition and liver damage (Omaye, 2004).

18. Sodium

Sodium was not reviewed by ATSDR or reported in the UK study because it is not considered to be hazardous. Sodium is GRAS in food in the US. Several salts of sodium are listed as GRAS for use in food in the US in 21 CFR Part 184. The IOM recommended an upper limit (UL) of 2,300 mg/day (IOM, 2005). However, adults in the US consume an average of 3,400 mg/day (IOM, 2013). In the WHO Guidelines for Drinking Water Quality, it was stated that sodium is not a health concern at levels found in drinking water (WHO, 2011).

19. Zinc

In the 2006 UK Total Diet Study, the population dietary exposure to zinc was 8.83 mg/day. The COT concluded that this dietary exposure to zinc is unlikely to be of toxicological concern. The JECFA Provisional Maximum Tolerable Daily Intake (PMTDI) for zinc was established at 0.3-1 mg/kg bw/day (18-60 mg/person/day; WHO, 1982). In the WHO Guidelines for Drinking Water Quality, the PMTDI was confirmed (WHO, 2011). In the US, ATSDR estimates an average dietary intake of 5.2-16.2 mg zinc per day (ATSDR, 2005c). The Expert Group on Vitamins and Minerals determined the safe upper level for daily consumption of zinc over a lifetime at 25 mg zinc/day for supplemental zinc (2003). Zinc toxicity can result from long-term intakes of 6 to 20 times the RDA (Omaye, 2004).

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Appendix I: Allergen Letter and Notice to the FDA

GRAS ASSOCIATES, LLC
12068 Via Cercina Drive
Bonita Springs, FL 34135-6922
216-470-7280
kraska@gras-associates.com

May 20, 2014

Dr. Paulette Gaynor
Division of Biotechnology & GRAS Notice Review (HFS-255)
Office of Food Additive Safety
Center for Food Additive Safety & Applied Nutrition
Food & Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: Request for Consultation on Duckweed Protein

Dear Dr. Gaynor:

I am communicating on behalf of our client Parabel regarding protein concentrate derived from Lemna minor commonly known as duckweed. It is our understanding that Marcus Kenny of Parabel met with you and your colleagues on February 10, 2014 to discuss submission of a possible GRAS notification on this alternative source of protein.

Mr. Kenny told us that one of the issues that arose in the discussion which was raised by your colleagues is the possible allergenicity of duckweed protein. It was suggested that Parabel may wish to conduct research on the protein structure a and determine if any structural relationship can be found to know allergenic protein found in food.

GRAS Associates has investigated the allergenicity question with the help of Dr. Steven Taylor, Co-Founder and Co-Director of the Food Allergy Research and Resource Program at the University of Nebraska .

First and foremost, the human consumption of duckweed in Southeast Asia, principally in Thailand, has not been associated with any known occurrence of allergies. In the recent thorough review (van der Spiegel et al., 2013), the human safety issues associated with popular sources of alternative proteins for use in food were examined. The authors discussed in detail the real possibility of allergenicity issues for several protein sources, but duckweed was not identified as a food source of concern. Regarding duckweed, the authors discussed many issues, principally bioconcentration of various pollutants that are found in areas where duckweed grows in the wild. The absence of discussion of allergenicity in this review is indicative of the lack of any reports of allergy or any scientific basis for suspicion of any allergic hazard from duckweed protein. In a tabulated summary of the prime safety issues of alternative sources of protein in the review (see Table 2 in van der Spiegel et al., 2013), allergenicity concerns for duckweed protein were conspicuously absent. We have conducted a literature search for scientific research on the allergenicity of proteins for duckweed. No papers were found on the subject. A brief review of several papers related to immunological activity of other components of duckweed is attached as Appendix A.

With regard to any testing or research into protein structure that could be done to obtain reassuring evidence that duckweed protein does not present an allergy hazard, Dr. Taylor advises that this is not technically feasible for the following reasons:

GRAS Associates, LLC
Duckweed Protein
May 20, 2014
Page 2

1. While it may be feasible to identify and study a novel protein that is produced from genetically modified organisms by comparing its amino acid sequence to the sequences of known allergens found in databases such as AllergenOnline, it is not possible to do the same on hundreds of proteins that may be produced by duckweed unless each of those proteins is isolated, purified, and sequenced, a task that would be very challenging and tedious.
2. Available testing techniques used to identify residues of known allergenic foods such as the allergen-specific ELISA assays are too specific to those sources of allergens and would not identify possible cross reactivity of proteins from other sources unless these novel proteins happened to be highly homologous with known allergenic foods. In such cases, the novel food would already be identified as a probable allergenic food because it would have a close botanical relationship to the novel food. This is not the case with duckweed.
3. Clinical testing for cross-reactivity in patients known to be allergic to other specific biological sources (foods or other) is only practical in cases where there is some reason to suspect possible cross-reactivity. That would happen in cases where there might be amino acid sequence homology between a novel protein and a known allergen, but as explained in item 1 above, that cannot easily be accomplished with mixtures of proteins of unknown sequence as exists with duckweed. That might also be reasonable considerations if there were known allergenic sources that were botanically related to duckweed. However, such relationships are not known to occur in the case of duckweed.
4. The resistance of novel proteins to pepsin digestion is often considered as a possible indication of allergenicity. However, pepsin digestion data is very difficult to interpret with mixtures of proteins.
5. While the experience in southeast Asia offers some confidence that duckweed meal or duckweed protein is not a potent allergenic food, the fact remains that almost all foods have some allergenic potential. Small numbers of consumers are allergic to any of a rather wide variety of foods. However, Parabel intends to use a common or usual name on the label of foods containing this ingredient to assure that if any allergy issue arises in the future that consumers will be able to recognize the source of the protein to avoid any consumption. This labeling approach is consistent with the FDA stance on using the ingredient label of foods to inform allergic consumers to potential hazards. In summary, we believe that there is no evidence to suspect an allergenicity issue with duckweed protein and that doing any prospective testing is not feasible and will not yield definitive results.

We request a conference call to discuss these issues with the scientific reviewers that were at the meeting of February 10. Please feel free to call me if you have any questions.

Sincerely,

(b) (6)

Richard Kraska, Ph. D., DABT
Chief Operating Officer and Co-Founder
GRAS Associates, LLC

Appendix A

Review of Possible Allergenicity of Duckweed Protein

May 20, 2014

Upon conducting a comprehensive research online and in several databases, we conclude that there is no scientific evidence that associates the proteins extracted from Lemna minor (duckweed) as possible allergens. The following databases were reviewed: Science Direct, PubMed, Scopus, UBC library, and Google Scholar. The review article on novel protein sources by Vander Spiegel et al. (2013) notes the use of duckweed as a traditional food in Southeast Asia and does not indicate a concern for the allergenicity of duckweed protein. The absence of any stated concern is conspicuous because these authors discuss allergenicity issues associated with other novel protein sources.

Several reports indicate that certain polysaccharides found in Lemna minor may have immunomodulatory activity (Popov et al., 2006 a,b,c) and effects on leukocytes not likely related to immune activity (Svedentsov et al., 2008). Lemna minor is used in oral and nasal spray products that are useful in the treatment of acute and chronic sinusitis (Suter and Bommer, 2003). None of these reports indicate any influence on IgE mediated pathways. Therefore there is no evidence that any component of duckweed would cause a food allergy or influence any food allergies.

References

Popov, S.V., Golovchenko, V.V., Ovodova, R.G., Smirnov, V.V., Khramova, D.S., Popova, G.Y., Ovodov, Y.S. 2006 "Characterisation of the oral adjuvant effect of lemnan, a pectic polysaccharide of *Lemna minor L.*," Vaccine 24: 5413-5419.

Popov, S.V., Günter, E.A., Markov, P.A., Smirnov, V.V., Khramova, D.S., Ovodov, Y.S. 2006 "Adjuvant Effect of Lemnan, Pectic Polysaccharide of Callus Culture of *Lemna minor* L. at Oral Administration." Immunopharmacology and Immunotoxicology 28:141–152.

Popov, S.V., Ovodova, R.G., Ovodov, Y.S. 2006 "Effect of Lemnan, Pectin fromLemna minor L., and its Fragments on Inflammatory Reaction." Phytotherapy Research 20: 403-407.

Svedentsov, E.P., Tumanova, T.V., Ovodova, R.G., Golovchenko, V.V., Zaitseva, O.O., Solomina, O.N., Stepanova, E.S., Ovodov, Y.S. 2008 "Cryoprotective Action of Lemnan, a Pectin from the Duckweed *Lemna minor*." Doklady Biological Sciences 421: 233-234.

Suter, A., Bommer, S. 2003 "Acute and chronic sinusitis: treatment with a homeopathic sinus spray." Schweiz. Zschr. GanzheitsMedizin 15: 233-238.

Appendix A
Duckweed Protein
May 20, 2014

Van der Spiegel, M., Noordam, M.Y., and van der Felx-Klerx, H.J. 2013 "Safety of Novel Protein Sources (Insects, Microalgae, Seaweed, Duckweed, and Rapeseed) and Legislative Aspects for Their Application in Food and Feed Production." Comprehensive Reviews in Food Science and Food Safety 12: 662-678.

APPENDIX J: Letter from the FSANZ authorities of ANZ

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai - Ahitereiria me Aotearoa

55 Blackall St., Barton
ACT 2600 Australia
PO Box 7186
Canberra BC ACT 2610
Australia
Tel + 61 2 6271 2222
Fax +61 2 6271 2278
www.foodstandards.gov.au

Level 6, 108 The Terrace
Wellington
PO Box 10 559
Wellington
Tel + 64 4 978 5630
Fax + 64 4 473 9855
www.foodstandards.govt.nz

Georgia Nanos
National Technical and Innovations Director
Additive Solutions Pty Ltd
43-45 Renver Road
CLAYTON VIC 3168

Dear Ms Nanos

Lentein™ Complete

Thank you for your email of 19 January 2017 enquiring whether in the view of the Advisory Committee on Novel Foods (the Committee)[1] Lentein™ Complete meets the definitions of 'non-traditional food' and 'novel food' in the Australia New Zealand Food Standards Code (the Code).

Standard 1.5.1 requires FSANZ to conduct a pre-market safety assessment of those non-traditional foods that are deemed to be novel according to the definitions in the Code. A copy of the definitions for 'non-traditional food' and 'novel food' are provided in the Attachment to this letter.

The Committee discussed your enquiry at its meeting on 15 March 2017 and used the guidance tool to assist in forming views in relation to red spinach extract. The guidance tool comprises of part 1 – determining whether a food is non-traditional or not; and part 2 – determining whether an assessment of public health and safety considerations is required for a non-traditional food.

The Committee has formed the view that Lentein™ Complete meets the definition of 'non-traditional food' on the basis that it does not have a history of human consumption as a food in Australia or New Zealand (Part 1 of the Guidance Tool). Part 2 of the Guidance Tool requires the Committee to consider whether Lentein™ Complete is a novel food and requires an assessment of public health and safety considerations. The Committee has undertaken a preliminary hazard identification process and formed the view that an assessment of public health and safety considerations is not required when Lentein™ Complete is used in a variety of foods at up to 24 grams per serve. Based on the information available it is likely that Lentein™ Complete is not considered to be within the scope of the definition of novel food for the purposes of the Code.

[1] The Advisory Committee on Novel Foods comprises representatives from Australian State and Territory jurisdictions, the New Zealand Ministry for Primary Industries and Food Standards Australia New Zealand. The Committee provides recommendations to the General Manager / Food Standards (Canberra) as to whether particular foods meet the definitions of 'non-traditional food' and 'novel food' in the Code.

It is the responsibility of manufacturers, suppliers or importers to ensure products comply with the requirements of the Code. FSANZ is not responsible for enforcing the requirements of the Code. Enforcement of the Code is the responsibility of the Commonwealth, State, Territory and New Zealand Governments. Accordingly, the interpretation and application of the Code, including decisions about the novelty of a food or food ingredient, is ultimately the responsibility of those jurisdictions. Therefore while the Committee may express a view about whether or not Lentein™ Complete meets the definition of a novel food for the purposes of the Code, it is ultimately a decision for the relevant enforcement authority.

If you wish to discuss this matter further, please contact Jonathon Kite on 02 6271 2646 or jonathon.kite@foodstandards.gov.au.

Yours sincerely

(b) (6)

Glen Neal
General Manager
Food Standards (Wellington)

4 April 2017

ATTACHMENT

non-traditional food means –

(a) a food that does not have a history of human consumption in Australia or New Zealand; or
(b) a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food; or
(c) any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand.

novel food means a non-traditional food and the food requires an assessment of the public health and safety considerations having regard to -

(a) the potential for adverse effects in humans; or
(b) the composition or structure of the food; or
(c) the process by which the food has been prepared; or
(d) the source from which it is derived; or
(e) patterns and levels of consumption of the food; or
(f) any other relevant matters.

Appendix L: Water Lentin (Duckweed) Recipes

Sautee Duckweed

From: http://www.ehow.com/how_8026515_cook-duckweed.html
How to Cook Duckweed by Christopher Godwin (Accessed 4/22/14)

1 lb. duckweed
3 cloves garlic, finely chopped
1-inch piece of ginger, finely chopped
½ shallot, minced
3 tbsp. olive oil
¼ c. dry white wine

Place duckweed in large glass container and cover with water. Allow to soften in refrigerator for 24 hrs.
Drain duckweed in a colander for one hour. Pat dry.
Heat olive oil in sauté pan over medium heat for one minute or until hot.
Add garlic, ginger, and shallots to the sauté pan. Cook for one minute or until the shallots are translucent but not browned.
Add the duckweed. Cook for 2 minutes, stirring constantly with a wooden spoon.
Add white wine to sauté pan. Cover and reduce heat to low. Allow the duckweed to steam in the wine for 5 minutes, or until the wine is evaporated.
Remove duckweed from heat and serve.

From: http://www.foragingtexas.com/2006/08/duckweed.html
Foraging Texas: Merriwether's Guide to Edible Wild Plants of Texas and the Southwest (Accessed 4/22/14)

Puree and add to soups and stews, sauté in oil or butter

Wild Eco-System Cuisine

From: http://www.urbanoutdoorskills.com/december2012.html
Urban Outdoor Skills (Accessed 4/22/14)

Oven roasted trout and fried trout skin with our special wild spices blend, wild watercress and veronica sauce, duckweed, fried curly dock in mugwort beer butter, curry dock nori, wild sages salt, sweet white clover salt.

Duckweed Soup

From: http://americanpreppersnetwork.net/viewtopic.php?t=34366
Duckweed Soup Recipe by Kappydell posted Wednesday Dec 26, 2012 at 11:48 pm (Accessed 4/22/14)

1 cup broccoli

Pages 000300 to 000303 have been removed in accordance with copyright laws. The removed references are:

Sree, K. Sowjanaya “Duckweed science and food excursion in Thailand” 2016. ISCDRA –Duckweed Forum Volume 4(3), issue 14, pages 274-275.

Appenroth, Klaus J “Duckweed for human nutrition” 2016. ISCDRA –Duckweed Forum Volume 4(4) pages 313-314.

2 cups onions, chopped
1 cup celery, chopped
2 Tsp ginger powder
1 large vegetable bouillon cube
2 Tbsp. soy sauce
1 Tbsp. oil
1 cup low-fat sour cream

Clean duckweed. Sauté duckweed and vegetables in oil with a cup of water. Cook at a simmer for 5 minutes. Cool. Puree in a blender. Add puree back to pan, stir in two cups of water, the bouillon cube, oil and soy sauce. Raise heat. Stir in cup of sour cream. Season to taste. Serve hot.

Asian Watermeal (Gang Kai Pum)
Made from *Wolffia globosa*
From: http://www.khiewchanta.com/archives/vegetarian/asian-watermeal-gang-kai-pum-1.html
Appon's Thai Food (Accessed 4/22/14)

100 g Asian watermeal (*Wolffia globosa*)
2 lemongrass
3 small red onion
3-5 chilies
3-4 Kaffir lime leaves
1 Tbsp. fish sauce
Dill
Basil

Chop the lemongrass into fine shreds. Pound and blend with red onion, chili, and kaffir leaves in a Thai mortar.
Rinse the watermeal and place in boiling water. Cook 3-5 minutes. Or dry fry watermeal for ~5 minutes.
Garnish with dill and basil.

Appendix M: EU Feed Material Registration www.feedmaterialsregister.eu

Name of feed material	Language	Feed material characteristics	Date of notification	Registration number
Lemna Feed	EN	Vegetable product derived from naturally growing various types of duckweed (Lemna species) in a bassin under controlled conditions. The product can be dried. The fresh product can be preserved (eg in pits). It will be a natural source of protein.	2012-05-21	02994-EN
Lemna Feed	NL	Vegetable product derived from naturally growing various types of duckweed (Lemna species) in a bassin under controlled conditions. The product can be dried. The fresh product can be preserved (eg in pits). It will be a natural source of protein.	2012-05-21	02995-NL
Lemna protein	EN	Vegetable product obtained by artificially drying fractions of duckweed juice (from Lemna species), which have been separated by pressing or centrifugation and precipitation of the proteins.	2016-01-11	06008-EN
Lemna protein	EN	Vegetable product obtained by artificially drying fractions of duckweed juice (from Lemna species), which have been separated by pressing or centrifugation and precipitation of the proteins.	2016-01-11	06009-EN
Lemna eiwit	NL	Vegetable product obtained by artificially drying fractions of duckweed juice (from Lemna species), which have been separated by pressing or centrifugation and precipitation of the proteins.	2016-01-11	06010-NL
Lemna vezels	NL	Vegetable product of the manufacture of duckweed protein (from Lemna species) consisting of extracted ground duckweed (Lemna species).	2016-01-11	06007-NL
Lemna fibres	EN	Vegetable product of the manufacture of duckweed protein (from Lemna species) consisting of extracted ground duckweed (Lemna species).	2016-01-11	06006-EN

Appendix N: LPC Animal Trials

1) Parabel 2015a. Influence of LPC on piglets performance. Trial report P-S-03.

INFLUENCE OF LPC ON PIGLETS PERFORMANCE

PARABEL CODE: P-S-03

ARC CODE: THS15-40

TRIAL CONDUCTED DURING MARCH 27 – MAY 1, 2014

AT

UDOM FARM

204/19 MU 1, TAMBON KLONG KIEW, BAN BUENG DISTRICT, CHONBURI PROVINCE, THAILAND.

BY

MR. SAKSIT SRINONGKOTE

ANIMAL RESEARCH AND CONSULTANT (ARC), 35/52 NOBLE HOUSE, PHAYATHAI ROAD,
KHET RATCHATHEWI, BANGKOK 10400, THAILAND, TEL +66 81 8480417; FAX +66 2 6400306
EMAIL: saksit_arc@hotmail.com

Influence of LPC on piglets performance

Saksit Srinongkote, Animal Research and Consultant (ARC), 35/52 Noble House, Phayathai Road, Khet Ratchathewi, Bangkok 10400, Thailand, Tel +66 81 8480417; Fax +66 2 6400306; email: saksit_arc@hotmail.com

Trial code: *THS13-29*

Background:

There is a commercial opportunity for LPC to replace fishmeal in weaning piglet diets. Parabel is focusing on South East Asia and a commercial pig farm in Thailand is chosen for this test. This study was conducted to measure the response of weaning piglets to LPC inclusion vs. fishmeal in a typical (South East Asia) commercial operation, with special attention to palatability.

Materials and methods

The trial was conducted in a commercial pig farm in Ban Bueng district, Chonburi province (Udom Farm) from March 27 to May 1, 2015. One hundred and twenty newly weaned crossbred piglets (LR x LW x DR), averaged 6.56 kg body weight, were allocated to two treatment diets, each diet with 4 replicate pens of 15 piglets per pen. Two treatment diets were formulated for each growing phase with fish meal or LPC level as shown in the table of treatment design below (table 1).

Table 1. Treatment design

Treatment	Diet	Fish meal		LPC	
		Prestarter (wk 1-2)	Starter (wk 3-4)	Prestarter (wk 1-2)	Starter (wk 3-4)
1	Practical corn-SBM-broken rice diet	4	2	-	-
2	Practical corn-SBM-broken rice diet	-	-	4	2

The composition and calculated nutrient content of the basal diets are shown in table 2. The experiment was conducted in an open-sided house with solid concrete floor pens. Each pen measured 2.0 m x 6.0 m and was equipped with a self feeder and 3 nipple water drinkers. Feed and water were provided *ad libitum*. All diets were used in pellet form. The average max/min temperatures in the pig house during the prestarter and starter periods were 35.9/24.5°C and 35.7/24.1%, respectively. Feed consumption as pen basis and individual body weight were measured at beginning (averaged 6.56 kg BW), at the end of day 14 and day 28. During the first 14 days of prestarter period, the overall health as pen basis was assessed with score 1-4, where 1 = 1 or less pigs off colour, no indication of ill health, lameness or scours, 2 = 2-3 pigs off colour, slight indication of ill health, lameness or scours, 3 = 4-5 pigs off colour, clear indication of ill health, lameness or scours, 4 = >5 off colour, serious signs of ill health, lameness or scours. Body weight, daily feed intake (DFI), average daily gain (ADG), feed conversion ratio (FCR), livability, performance index and overall health score were calculated and were subjected to analysis of variance as a randomized complete block design.

Table 2. Composition and calculated nutrient content of diets

Code	Ingredients	Price	Pre-starter 7-10 kg (wk 1-2)		Starter 10-20 kg (wk 3-4)	
		(B/kg)	Corn-soy with fish meal	Corn-soy with LPC	Corn-soy with fish meal	Corn-soy with LPC

B120	Corn (7.7%CP)	11.4	21.884	20.295	40.535	39.740
B421	Dehull-Soybean meal (48.9%CP)	19.3	21.442	22.056	22.197	22.504
B105	Broken rice (7.7%CP)	14.5	25.000	25.000	15.000	15.000
B417	Full fat soybean (36.0%CP)	20.75	10.000	10.000	5.000	5.000
B127	Rice bran, full fat (13.6%CP)	10.2	5.000	5.000	6.000	6.000
B303	Whey powder sweet	56	5.000	5.000	3.000	3.000
B306	Fish meal (58%CP)	36	4.000		2.000	
B306	Lemna protein concentrate (LPC)			4.000		2.000
B202	Soybean oil	48	3.373	3.750	1.965	2.153
B602	Lime stone (Ca 36.4%)	1.5	1.104	1.334	1.112	1.227
B601	MDCP (P 16.3%, Ca 21.8%)	19	1.090	1.383	1.078	1.224
B603	Salt	5	0.281	0.335	0.271	0.298
B701	SP Premix	241	0.500	0.500	0.500	0.500
B807	Pellet binder	70	0.300	0.300	0.300	0.300
B806	Zinc Oxide	74	0.230	0.230	0.230	0.230
B501	L-Lysine HCl	52	0.271	0.310	0.324	0.343
B502	DL-Methionine	122	0.157	0.174	0.140	0.149
B503	L-Threonine	67	0.143	0.133	0.141	0.135
B504	L-Tryptophan	750	0.039	0.014	0.044	0.031
B901	Tiamulin10%	230	0.100	0.100	0.100	0.100
B906	Colistin-20%	900	0.050	0.050	0.030	0.030
B905	Amoxycillin-50%	2300	0.035	0.035	0.035	0.035
	Total		100.000	100.000	100.000	100.000
	Current cost, baht/kg		22.73	21.32	19.96	19.25
	Nutrients	Unit				
1	Weight	Kg	1	1	1	1
2	Dry Matter	%	89.1	89.0	88.7	88.7
5	ME.For Swine	Kcal/Kg	3400	3400	3300	3300
9	Crude Protein	%	22.00	22.00	20.00	20.00
11	Crude Fat	%	7.84	8.20	6.09	6.27
12	Linoleic Acid	%	3.07	3.23	2.35	2.43
13	Crude Fiber	%	2.63	2.60	2.73	2.72
31	Dig.Lys (Swine)	%	1.30	1.30	1.20	1.20
32	Dig.Met (Swine)	%	0.49	0.48	0.44	0.44
33	Dig.Cys (Swine)	%	0.30	0.30	0.29	0.29
34	Dig.M+C (Swine)	%	0.78	0.78	0.72	0.72
35	Dig.Thr (Swine)	%	0.85	0.85	0.78	0.78
36	Dig.Trp (Swine)	%	0.26	0.26	0.24	0.24
37	Dig.Arg (Swine)	%	1.35	1.37	1.23	1.24
38	Dig.Val (Swine)	%	0.89	0.92	0.83	0.84
39	Dig.Ile (Swine)	%	0.80	0.82	0.74	0.75
40	Dig.Leu (Swine)	%	1.47	1.48	1.43	1.43
41	Dig.His (Swine)	%	0.50	0.49	0.46	0.46
42	Dig.Phe (Swine)	%	0.97	0.92	0.88	0.86
46	Lysine	%	1.49	1.49	1.36	1.36
47	Arginine	%	1.51	1.52	1.36	1.36
48	Methionine	%	0.53	0.53	0.48	0.47
49	Met + Cys	%	0.89	0.89	0.81	0.81
50	Cystine	%	0.35	0.36	0.33	0.33
51	Phe + Tyr	%	1.49	1.58	1.38	1.43
52	Threonine	%	1.00	1.01	0.91	0.91
53	Tryptophan	%	0.30	0.30	0.28	0.28
55	Histidine	%	0.57	0.56	0.53	0.52
56	Isoleucine	%	0.94	0.97	0.84	0.85
57	Leucine	%	1.68	1.70	1.57	1.59
58	Valine	%	1.06	1.09	0.96	0.97
59	Phenylalanine	%	0.98	0.99	0.87	0.88
66	Calcium	%	0.90	0.90	0.80	0.80
67	Phosphorus-total	%	0.75	0.78	0.71	0.72
68	Phosphorus-avail.	%	0.42	0.42	0.36	0.36
78	Sodium	%	0.20	0.20	0.16	0.16
79	Chloride	%	0.26	0.29	0.23	0.24
80	Salt	%	0.55	0.60	0.44	0.47

Results

Table 3. Effect of LCP on performance of piglets (week 1-2)

Treatment		Initial	Final	ADG	DFI	FCR	Livability	Performance
Group	Diet	BW (kg)	BW (kg)	(kg)	(kg)		(%)	Index[1] (%)
1	Fish meal diet (4% FM)	6.56	11.47	0.350	0.425	1.219	100.00	28.94
2	LPC diet (4% LPC)	6.56	12.09	0.395	0.438	1.109	100.00	35.75
	P-value		*0.0891*	*0.0909*	*0.1558*	*0.1303*	*1.0000*	*0.0928*
	Pooled SEM		*0.179*	*0.013*	*0.005*	*0.038*	*0.000*	*1.976*
	C.V.%		*3.04*	*6.87*	*2.09*	*6.45*	*0.00*	*12.22*

[1] Performance index = (Body weight gain x Livability) / (FCR x Test period)

Table 4. Effect of LCP on performance of piglets (week 3-4)

Treatment		Initial	Final	ADG	DFI	FCR	Livability	Performance
Group	Diet	BW (kg)	BW (kg)	(kg)	(kg)		(%)	Index[1] (%)
1	Fish meal diet (2% FM)	11.47	18.85[b]	0.527	0.943	1.793	100.00	29.46
2	LPC diet (2% LPC)	12.09	20.25[a]	0.583	0.971	1.679	100.00	35.27
	P-value	*0.0891*	*0.0227*	*0.0964*	*0.2906*	*0.1555*	*1.0000*	*0.1427*
	Pooled SEM	*0.179*	*0.230*	*0.016*	*0.015*	*0.042*	*0.000*	*2.080*
	C.V.%	*3.04*	*2.35*	*5.94*	*3.18*	*4.88*	*0.00*	*12.85*

[a,b] Means within column with no common superscript differ significantly (P<0.05).
[1] Performance index = (Body weight gain x Livability) / (FCR x Test period)

Table 5. Effect of LCP on performance of piglets (week 1-4)

Treatment		Initial	Final	ADG	DFI	FCR	Livability	Performance
Group	Diet	BW (kg)	BW (kg)	(kg)	(kg)		(%)	Index[1] (%)
1	Fish meal diet (4/2% FM)	6.56	18.85[b]	0.439[b]	0.684	1.561[a]	100.00	28.13[b]
2	LPC diet (4/2% LPC)	6.56	20.25[a]	0.489[a]	0.704	1.442[b]	100.00	34.00[a]
	P-value		*0.0227*	*0.0216*	*0.2380*	*0.0114*	*1.0000*	*0.0172*
	Pooled SEM		*0.230*	*0.008*	*0.010*	*0.015*	*0.000*	*0.863*
	C.V.%		*2.35*	*3.47*	*2.74*	*2.01*	*0.00*	*5.56*

[a,b] Means within column with no common superscript differ significantly (P<0.05).
[1] Performance index = (Body weight gain x Livability) / (FCR x Test period)

Table 6. Effect of LCP on diarrhea and overall health scores of piglets (week 1-2)

Treatment		Diarrhea and health Score[1]
Group	Diet	
1	Fish meal diet (4/2% FM)	1.70
2	LPC diet (4/2% LPC)	1.66
	P-value	*0.495*
	Pooled SEM	*0.032*
	C.V.%	*3.81*

[1]*Score 1-4, where 1 = 1 or less pigs off colour, no indication of ill health, lameness or scours, 2 = 2-3 pigs off colour, slight indication of ill health, lameness or scours, 3 = 4-5 pigs off colour, clear indication of ill health, lameness or scours, 4 = >5 off colour, serious signs of ill health, lameness or scours.*

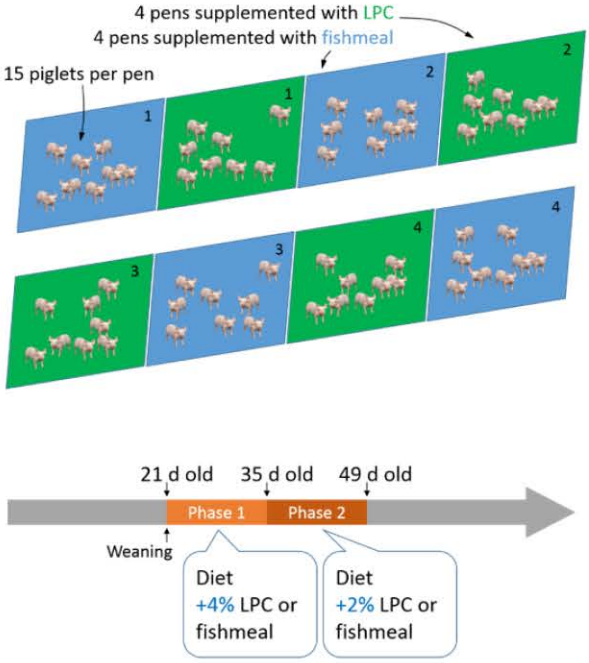
TRIAL P-S-03

INFLUENCE OF LPC ON WEANING PIGLETS PERFORMANCE

This trial was designed to test the response of just weaned piglets to a diet supplemented with LPC (UFD) vs. fishmeal in commercial conditions

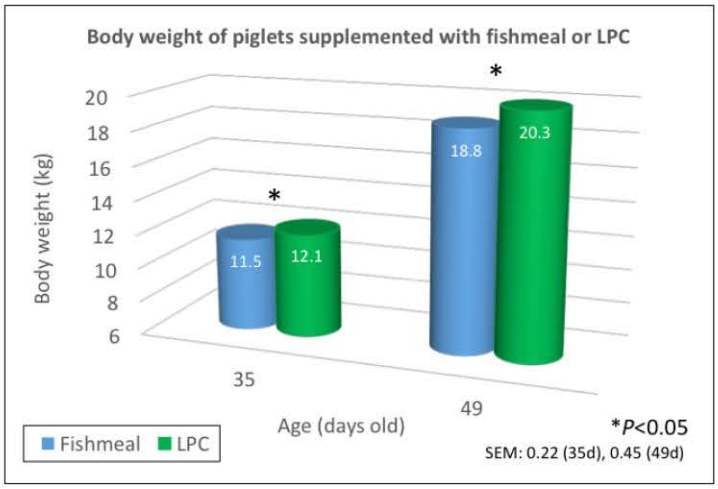
TRIAL SET-UP

- ✓ The trial was run in a commercial pig farm in Thailand
- ✓ Half of the piglets received a customary diet supplemented with fishmeal (4% in phase 1 and 2%) in phase 2), and the other half had the fishmeal replaced for LPC at the same inclusion levels
- ✓ Diet was based on the composition of a typical South East Asia diet: corn (21% and 40% in phase 1 and 2, respectively), soybean meal (22% and 22%), broken rice (25% and 15%), and full fat soybeans (10% and 5%)



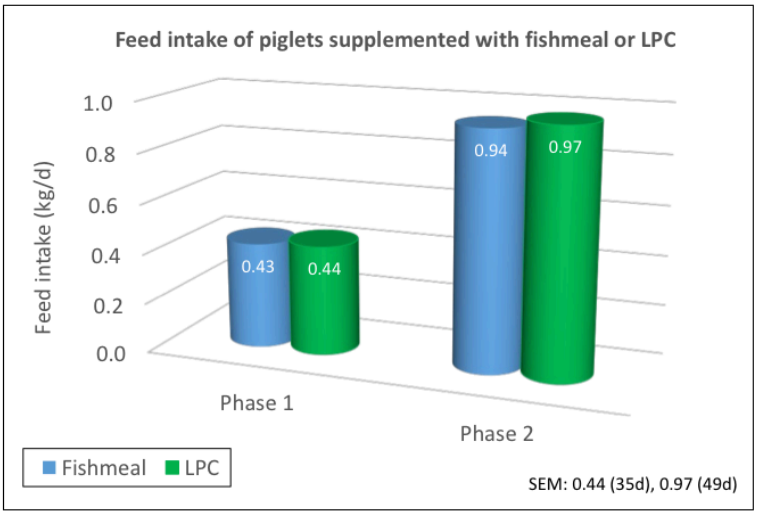
RESULTS

- ✓ The piglets grew more ($P<0.05$) when supplemented LPC instead of fishmeal

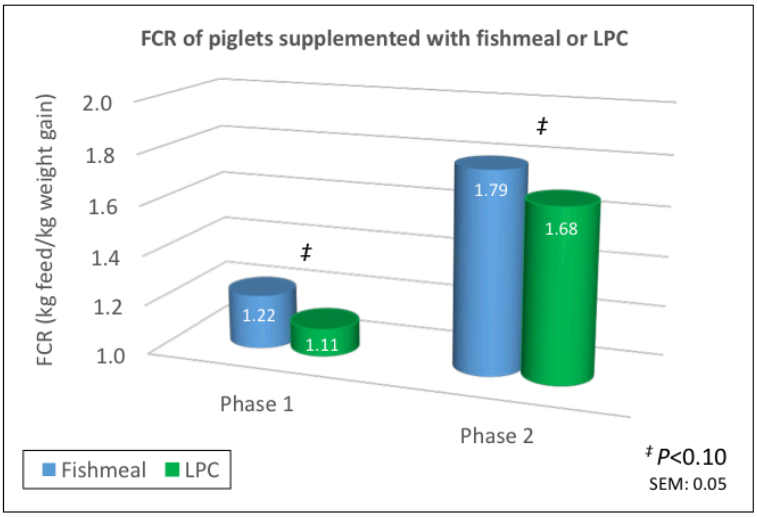


TRIAL P-S-03

✓ However, the piglets ate the same (P>0.05) either on the fishmeal- or LPC- supplemented diet



✓ As a result, the feed conversion ratio FCR tended (P<0.10) to decrease in LPC supplemented piglets (less is better)



CONCLUSION

LPC outperformed fishmeal as a dietary supplement for weaned piglets

2) Parabel 2015b. Influence of LPC on broiler performance. Trial report P-P-03.

INFLUENCE OF LPC ON BROILER PERFORMANCE

PARABEL CODE: P-P-03

ARC CODE: THB15-42

TRIAL CONDUCTED DURING APRIL 3 – MAY 8, 2015

AT

NKP FARM

NIKOMPATTANA DISTRICT, RAYONG PROVINCE, THAILAND

BY

SAKSIT SRINONGKOTE

ANIMAL RESEARCH CONSULTANT (ARC)
35/52 NOBLE HOUSE PHAYATHAI (10K), PHAYATHAI ROAD, KHET RATCHATHEWI,
BANGKOK 10400, THAILAND, TEL: +66 8 18480417; FAX: +66 2 6400306
EMAIL: saksit_arc@hotmail.com

Influence of LPC on broiler performance

Saksit Srinongkote, Animal Research and Consultant (ARC), 35/52 Noble House, Phayathai Road, Khet Ratchathewi, Bangkok 10400, Thailand, Tel: +66 81 8480417; Fax: +66 2 6400306; email: saksit_arc@hotmail.com

Trial Code: *THB15-42*

Background:

Previous assessments of LPC on broiler performance showed positive response to lower inclusion rates (1-2%) relative to higher inclusion levels >3%. The previous trial results have also indicated that live weight gain diminished as inclusion levels increased however feed intake was maintained. This would suggest that LPC 1) nutrient contribution to the formulation was over estimated, 2) formulation of the treatment diets was problematic from a nutrient balance point of view 3) there is a negative effect of LPC on growth due to presence of an unknown metabolite. This trial was conducted to measure the response of male Ross 308 birds to LPC inclusion in typical commercial Southeast Asian broiler diets.

Materials and methods

Two hundred and forty (240) newly hatched broiler chicks of commercial strain (Ross 308) were randomly allocated to 3 treatments with 8 replications using 10 male chicks in a pen as an experimental unit. Three test diets for each growing phase were formulated with fish meal or LPC as shown in the table of treatment design below (table 1).

Table 1. Treatment design

	Test ingredients		
	Starter (0 to 10d)	Grower (10 to 24d)	Finisher (24 to 35d)
Treatment 1	0	0	0
Treatment 2	Fish meal 2%	Fish meal 1%	0
Treatment 3	LPC 2%	LPC 1%	0

The trial was arranged as a RCBD experiment at the broiler research facility of NKP Farm, Rayong province. The test diets were prepared and processed by BARC feed mill. The composition and nutrient content of experimental diets are shown in table 2. The test diets were provided to birds up to 24 days of age. After day 24, birds in all treatment groups were fed the same practical finisher diet until the end of finisher period (35 days of age). The experiment was conducted in a closing house with tunnel ventilation and evaporative cooling system. Birds were raised on solid-concrete-floor pens using rice hull as bedding material. Each pen measured 1.0 m x 1.0 m and was equipped with a self-feeder and two nipple water drinkers. Feed and water were provided *ad libitum*. All experimental diets were processed under conditioning temperature of 82°C and made to pellets of 3.2 mm diameter. Feeds were provided to birds in crumble form during the first 10 days and in pellet form thereafter until finishing 35 days test period. Sacox (salinomycin 12%) was used in feed at the level of 500 g/t to control coccidiosis. Lighting program of 20L/4D was provided. All birds were vaccinated for Newcastle and Infectious Bronchitis diseases at 7 days of age and Gumboro disease at 14 days of age. The average max/min temperature and max/min relative humidity in the experimental house were 32.4/29.5ºC and 69.5/43.6% in the first period (0-10 days), 29.3/25.7 and 77.5/41.1% in the grower period (10-24 days) and 29.6/26.1ºC and 85.5/56.4% in the finisher period (24-35 days), respectively. Feed consumption and body weight as pen basis were measured during the period of 0-10, 10-24 and 24-35 days of age to calculate body weight gain (average final body weight – average initial body weight) and FCR (pen feed intake / pen weight gain). Individual feed intake was calculated by average body weight gain x FCR. Livability was calculated by 100 – (% death + % culls). All data were analyzed using the GLM procedure of SAS software (SAS Institute, 1996) for analysis of variance as a randomized complete block design. Significant differences among treatments were identified at 5% level by Duncan's multiple range tests.

Table 2. Composition and calculated nutrient content of diets

		0 - 10 days			10 – 24 days			24-35 days
		T1	T2	T3	T1	T2	T3	T1-T3
Code	INGREDIENTS	S520	S500	S510	G521	G501	G511	F502
10	Corn 7.5%	55.44	56.90	57.33	61.28	61.76	61.64	64.24
11	Soybean meal 48.5%	36.86	34.28	33.90	30.73	29.67	29.61	27.08
12	LPC 53.1% as is	0.00	0.00	2.00	0.00	0.00	1.00	0.00

123	SE Asia fish meal 58%	0.00	2.00	0.00	0.00	1.00	0.00	0.00
178	Limestone	1.44	1.31	1.48	1.29	1.23	1.31	1.20
181	Salt	0.19	0.17	0.15	0.17	0.17	0.16	0.19
182	Sodium Bicarbonate	0.26	0.24	0.26	0.36	0.35	0.36	0.27
209	Choline chloride	0.08	0.10	0.10	0.12	0.13	0.13	0.11
212	L-Lysine HCl	0.22	0.21	0.23	0.26	0.25	0.26	0.23
213	L-Threonine	0.10	0.09	0.09	0.10	0.10	0.10	0.08
218	DL-Methionine	0.33	0.32	0.33	0.31	0.30	0.31	0.26
252	Sacox (salinomycin 12%)	0.05	0.05	0.05	0.05	0.05	0.05	0.05
274	V/M premix	0.20	0.20	0.20	0.20	0.20	0.20	0.20
504	Soybean oil	3.23	2.77	2.76	3.67	3.47	3.46	4.74
505	Monodicalciumphosphate	1.61	1.37	1.52	1.45	1.33	1.41	1.37
	Total	100.00	100.00	100.40	100.00	100.00	100.00	100.00
	Nutrients							
	Dry matter, %	89.61	89.55	89.47	89.54	89.51	89.50	89.55
	Crude protein, %	22.89	22.98	22.71	20.49	20.62	20.51	18.91
	Crude fat, %	6.50	6.28	5.89	7.11	7.03	7.01	8.26
	ME for poultry, kcal/kg	3020	3018	3020	3101	3100	3101	3199
	Crude fiber, %	2.66	2.61	2.62	2.55	2.53	2.53	2.47
	Ash, %	6.23	6.08	6.31	5.66	5.60	5.72	5.23
	Calcium, %	0.95	0.95	0.95	0.85	0.85	0.85	0.79
	Total P, %	0.74	0.73	0.74	0.68	0.68	0.68	0.65
	Dig. P, %	0.47	0.47	0.47	0.43	0.43	0.43	0.40
	Ca:P ratio	2.02	2.02	2.02	2.00	2.00		1.98
	Salt	0.37	0.37	0.37	0.36	0.36	0.36	0.37
	Sodium, %	0.16	0.16	0.16	0.18	0.18	0.18	0.16
	Chloride, %	0.23	0.23	0.23	0.23	0.23	0.23	0.23
	Potassium, %	0.95	0.92	0.95	0.84	0.83	0.85	0.77
	Na:K:Cl	10.47	9.97	10.33	9.54	9.32	9.52	8.55
	Lysine	1.38	1.37	1.37	1.25	1.24		1.12
	Methionine	0.65	0.66	0.66	0.61	0.61		0.53
	Met+Cys	1.02	1.02	1.02	0.94	0.94		0.85
	Arginine	1.51	1.43	1.48	1.32	1.28		1.20
	Threonine	0.94	0.93	0.94	0.85	0.84		0.76
	Tryptophan	0.26	0.26	0.27	0.23	0.23		0.21
	Isoleucine	0.97	0.91	0.95	0.85	0.83		0.78
	Leucine	1.83	1.75	1.83	1.67	1.64		1.57
	Histidine	0.60	0.57	0.59	0.53	0.52		0.49
	Valine	1.07	1.01	1.07	0.95	0.93		0.88
	Cystine	0.36	0.35	0.36	0.33	0.33		0.31
	Dig. Lys	1.27	1.27	1.27	1.15	1.15		1.03
	Dig. Met	0.63	0.64	0.64	0.59	0.59		0.52
	Dig. Cys	0.32	0.32	0.32	0.29	0.29		0.28
	Dig. M+C	0.94	0.94	0.94	0.87	0.87		0.78
	Dig. Thr	0.84	0.84	0.84	0.76	0.76		0.68
	Dig. Trp	0.24	0.24	0.25	0.21	0.21		0.19
	Dig. Ile	0.89	0.88	0.88	0.78	0.78		0.71
	Dig. Arg	1.40	1.39	1.37	1.22	1.22		1.11
	Dig. Leu	1.71	1.71	1.71	1.56	1.57		1.47
	Dig. Val	0.97	0.97	0.97	0.86	0.87		0.80
	Choline	1600	1600	1600	1600	1600		1500
	C18:2	3.07	2.86	2.67	3.35	3.25		3.89
	C18:3	0.31	0.28	0.27	0.34	0.32		0.41

Results

Table 3. Influence of LPC on performance of broilers (0 - 10 days of age)

Treatment		Initial	Final	Body	Feed	Feed	Livability
Group	Diet	body	body	weight	intake	conversion	

	weight (g)	weight (g)	gain (g)	(g)	ratio[1]	(%)
1	0.049	0.428	0.379	0.405	1.070 [b]	98.75
2	0.049	0.429	0.380	0.411	1.082 [b]	100.00
3	0.049	0.417	0.368	0.409	1.111 [a]	100.00
P-value		*0.0595*	*0.0627*	*0.7887*	*0.0090*	*0.3927*
Pooled SEM		*0.004*	*0.004*	*0.006*	*0.008*	*0.722*
C.V.%		*2.43*	*2.78*	*3.98*	*2.12*	*2.05*

[a,b] Means within column with no common superscript differ significantly (P<0.05).
[1] Feed conversion ratio corrected for mortality and culls.

Table 4. Influence of LPC on performance of broilers (10 - 24 days of age)

Treatment		Initial body weight (g)	Final body weight (g)	Body weight gain (g)	Feed intake (g)	Feed conversion ratio[1]	Livability (%)
Group	Diet						
1		0.428	1.586	1.158	1.597	1.379	100.00
2		0.429	1.580	1.151	1.593	1.383	100.00
3		0.417	1.557	1.140	1.586	1.392	98.75
P-value		*0.0595*	*0.2624*	*0.6134*	*0.8778*	*0.4704*	*0.3927*
Pooled SEM		*0.004*	*0.013*	*0.013*	*0.016*	*0.007*	*0.722*
C.V.%		*2.43*	*2.28*	*3.10*	*2.83*	*1.44*	*2.05*

[1] Feed conversion ratio corrected for mortality and culls.

Table 5. Influence of LPC on performance of broilers (0 - 24 days of age)

Treatment		Initial body weight (g)	Final body weight (g)	Body weight gain (g)	Feed intake (g)	Feed conversion ratio[1]	Livability (%)
Group	Diet						
1		0.049	1.586	1.537	2.002	1.303	98.75
2		0.049	1.580	1.531	2.003	1.308	100.00
3		0.049	1.557	1.508	1.994	1.323	98.75
P-value			*0.2624*	*0.2610*	*0.9012*	*0.0507*	*0.6365*
Pooled SEM			*0.013*	*0.013*	*0.016*	*0.005*	*1.056*
C.V.%			*2.28*	*2.34*	*2.29*	*1.15*	*3.01*

[1] Feed conversion ratio corrected for mortality and culls.

Table 6. Influence of LPC on performance of broilers (24 - 35 days of age)

Treatment		Initial body weight (g)	Final body weight (g)	Body weight gain (g)	Feed intake (g)	Feed conversion ratio[1]	Livability (%)
Group	Diet						
1		1.586	2.448	0.862	1.710	1.994	98.75
2		1.580	2.452	0.872	1.724	1.985	100.00
3		1.557	2.450	0.893	1.758	1.973	98.75

P-value	*0.2624*	*0.9941*	*0.4112*	*0.5728*	*0.8778*	*0.6365*
Pooled SEM	*0.013*	*0.023*	*0.016*	*0.032*	*0.029*	*1.056*
C.V.%	*2.28*	*2.62*	*5.24*	*5.27*	*4.14*	*3.01*

[1] Feed conversion ratio corrected for mortality and culls.

Table 7. Influence of LPC on performance of broilers (0 - 35 days of age)

Treatment		Initial body weight (g)	Final body weight (g)	Body weight gain (g)	Feed intake (g)	Feed conversion ratio[1]	Livability (%)
Group	Diet						
1		0.049	2.448	2.399	3.710	1.547	97.50
2		0.049	2.452	2.403	3.727	1.552	100.00
3		0.049	2.450	2.401	3.746	1.561	97.50
P-value			*0.9941*	*0.9941*	*0.8078*	*0.5982*	*0.3927*
Pooled SEM			*0.023*	*0.023*	*0.039*	*0.010*	*1.443*
C.V.%			*2.62*	*2.68*	*2.95*	*1.81*	*4.15*

[1] Feed conversion ratio corrected for mortality and culls.

Appendix O:

1) Oral Toxicity Study with LENTEIN™ Complete

SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH:DELHI

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Draft Study Report

Study Number : 1704-1-451-1004
Study Title : Repeated Dose (90 days) Oral Toxicity Study with Lentein complete in Wistar rats
Test Item : Lentein complete
Study Director : Dr. Pooja

Sponsor's Name & Address:

M/s Parabel USA Inc.
7898 Headwaters Commerce Street
Fellsmare, FL 32948
USA

Regulatory Guidelines

OECD Guidelines for Testing of chemicals, Repeated Dose 90 Days Oral toxicity Study in Rodents (No. 408, Section 4: Health Effects) adopted on 21st September, 1998

SHRIRAM
ISO 9001

Test Facility's Name & address:

Toxicology Centre
Shriram Institute for Industrial Research
(A Unit of Shriram Scientific & Industrial Research Foundation)
19, University Road, Delhi – 110007
Email ID: sridlhi@vsnl.com
Tel. 27667267, 27667860, 27667432
Fax No. +91-11-27667676, 27667207

Page 1 of 236

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STUDY No. : 1704-1-451-1004
TEST ITEM : LENTEIN COMPLETE
STUDY TITLE : REPEATED DOSE (90 DAYS) ORAL TOXICITY STUDY WITH LENTEIN COMPLETE IN WISTAR RATS
REPORT No. :
DATE OF COMPLETION OF STUDY:

STATEMENT OF QUALITY ASSURANCE UNIT

Quality Assurance Unit of the testing facility inspected the conduct of study entitled 'Repeated Dose (90 Days) Oral Toxicity Study with "Lentein Complete" in Wistar Rats' on the following dates:

Sr. No.	Critical Phases of study	Dates of Inspection	Dates of Reporting	
			Study Director	Management
1.	Draft Study Plan	16.04.2017	16.04.2017	16.04.2017
2.	Animal Husbandry	01.05.2017	01.05.2017	01.05.2017
3.	Dosing	06.05.2017	06.05.2017	06.05.2017
4.	Toxic Signs & Symptoms	06.05.2017	06.05.2017	06.05.2017
5.	Necropsy	20.08.2017	20.08.2017	20.08.2017
6.	Raw data	22.09.2017	22.09.2017	22.09.2017
7.	Draft Report	16.10.2017	16.10.2017	16.10.2017
8.	Final Report			

This study was conducted in accordance to approved study plan and the Standard Operating Procedures for non-clinical laboratory studies. No findings were noticed during inspection, which would have impaired this study in any way.
This statement confirms that the final report reflects the raw data of the study.

(b) (6)

Dr. M.L. Aggarwal — Head Quality Assurance Unit

Signature

17.10.2017 — Date

SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH:DELHI

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STUDY TITLE : REPEATED DOSE (90 DAYS) ORAL TOXICITY STUDY WITH LENTEIN COMPLETE IN WISTAR RATS
REPORT No. :
DATE OF COMPLETION OF STUDY:

STATEMENT OF COMPLIANCE

The study entitled 'Repeated Dose (90 Days) Oral Toxicity Study with "Lentein Complete" in Wistar Rats' was performed in accordance with the approved study plan and standard operating procedures of Toxicology Centre, Shriram Institute for Industrial Research.

We hereby attest the authenticity of the study and guarantee that this report represents a true and accurate record of results obtained and shall not be reproduced except in full, without the written approval of the sponsor.

The study was conducted to meet the requirement of OECD Guidelines for Testing of chemicals, Repeated Dose 90 Days Oral toxicity Study in Rodents (No. 408, Section 4: Health Effects). All original study raw data, signed study plan, study schedule, observation sheets, tissue blocks, specimens, slides together with the copy of final study report and the representative test item will be archived in the archives of Toxicology Centre, Shriram Institute for Industrial Research.

There were no known circumstances that may have affected the quality or integrity of the study. The sponsor is responsible for necessary evaluations of the test item concerning the chemical purity, identity, stability and other required data.

	(b) (6)	
Dr. Pooja		**17.10.2017**
Study Director	Signature	Date

	(b) (6)	
Dr. K. M. Chacko		**17.10.2017**
Test Facility Management	Signature	Date

SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH:DELHI

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STUDY TITLE : REPEATED DOSE (90 DAYS) ORAL TOXICITY STUDY WITH LENTEIN COMPLETE IN WISTAR RATS
REPORT No. :
DATE OF COMPLETION OF STUDY:

KEY PERSONNEL INVOLVED IN THE STUDY

DESIGNATION	NAME & ADDRESS
Study Director	**Dr. Pooja, M.Sc., PhD** Toxicology Centre Shriram Institute for Industrial Research 19, University Road, Delhi – 110007 Email ID: sridlhi@vsnl.com Tel. 27667267, 27667860, 27667432 Fax No. 91+11-27667676, 27667207
Study Personnel	**Ms. Deepti, M.Sc.** Toxicology Centre Shriram Institute for Industrial Research 19, University Road, Delhi – 110007 Email ID: sridlhi@vsnl.com Tel. 27667267, 27667860, 27667432 Fax No. 91+11-27667676, 27667207
Laboratory Technician	**Mr. Heera lal, M.Sc.** **Mr. Rajeev Bisht, BMLT** Toxicology Centre Shriram Institute for Industrial Research 19, University Road, Delhi – 110007 Email ID: sridlhi@vsnl.com Tel. 27667267, 27667860, 27667432 Fax No. 91+11-27667676, 27667207
Study Pathologist	**Dr. B. N. Panda, M.V.Sc.** **Dr. S. S. Rathore, M.V.Sc.** Toxicology Centre Shriram Institute for Industrial Research 19, University Road, Delhi – 110007 Email ID: sridlhi@vsnl.com Tel. 27667267, 27667860, 27667432 Fax No. 91+11-27667676, 27667207

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INDEX

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DATE OF COMPLETION OF STUDY:

SUMMARY

This study was conducted to assess the toxicological effects of 'Lentein Complete', when the test item was administered to Wistar rats orally for 90 consecutive days (7 days /week), so as to establish safety criteria.

Prior to conducting the main study, a dose range finding study was conducted in Wistar rats which were randomly distributed into four groups of 3 animals/ sex/ group. Three groups of 6 rats each (3 male and 3 female) were administered with Lentein Complete at the dose levels of 100 mg/kg B.wt (low dose), 500 mg/kg B.wt (intermediate dose) and 1000 mg/kg B.wt (high dose) respectively for 14 days consecutively with the help of cannula. Similarly, a fourth group of 6 rats (3 male and 3 female) designated as control group were orally administered with corn oil (vehicle) only for 14 days. After 14 days the test and control group animals were necropsied. No treatment related toxic sign and symptoms/mortality were observed.

Main study was conducted with 100 (50 male and 50 female) Wistar rats which were randomly distributed into six groups. Three groups of 20 rats each (10 male and 10 female) were administered with "Lentein Complete" orally at the dose levels of 100 mg/kg B.wt (low dose), 500 mg/kg B.wt (intermediate dose) and 1000 mg/kg B.wt (high dose) respectively for seven days a week for 90 days with the help of cannula. Similarly, a control group of 20 rats (10 male and 10 female) was orally administered with corn oil only (vehicle) for 90 days and was designated as vehicle control group.

Two additional recovery groups i.e. 'Satellite Control' and 'Satellite High dose' each comprised of 10 rats (5 male and 5 female) were also administered with corn oil and test item i.e. Lentein Complete at the dose level of 1000 mg/kg B.wt respectively for 90 days.

After 90 days, the treatment and vehicle control group of animals were sacrificed. Both the satellite groups of animals were kept under observation for an additional 28 days, so as to check the reversibility, persistence or delayed toxic effect.

Criteria used to evaluate compound related effects included; appearance, behaviour, toxic sign and symptoms, morbidity, mortality, body weights, feed consumption, haematological and biochemical analysis, urine analysis, neurobehavioral observation, ophthalmological examination, organ weights, necropsy and histopathology.

The animals were observed daily for behaviour, appearance and toxicological signs and symptoms. No treatment related toxic sign and symptoms were observed in low dose (100 mg/kg B.wt), intermediate dose (500 mg/kg B.wt), high dose (1000 mg/kg B.wt.) and satellite high dose (1000 mg/kg B.wt.) group animals when compared to their control counter

parts. No mortality was observed in any of the treatment groups as well as control and satellite high dose animals during the study period (Appendix: 1).

Body weights of all the treatment and control group animals were recorded weekly. Body weight gain of the treatment group animals (Low dose, Intermediate dose and High dose) was comparable to control group animals (Appendix: 2).

Blood for haematological and biochemical investigations were withdrawn from the animals at days 91 and 119 (for satellite group) from abdominal vein.

The haematological parameters of low dose (100 mg/kg B.wt.), intermediate dose (500 mg/kg B.wt.), and high dose (1000 mg/kg B.wt.) groups were comparable to control group of animals at terminal evaluation. Similarly, the parameters of satellite high dose (1000 mg/kg B.wt.) animals were comparable to their control counter parts (Appendix: 3).

The biochemical parameters of low dose (100 mg/kg B.wt.), intermediate dose (500 mg/kg B.wt.), high dose and satellite high dose groups (1000 mg/kg B.wt.) were comparable to control group of animals at terminal sacrifice evaluation. No changes were found in any parameters of satellite groups (Appendix: 4).

The organ weights of the animals of all the treatment groups were comparable to the control group. The organ weights of the animals in satellite high dose group were comparable to the satellite control group animals (Appendix: 5).

Feed consumption of the animals was recorded for 90 days, for the satellite groups the consumption was recorded for an additional 28 days (Appendix: 6).

Feed consumption of the animals of low dose, intermediate dose, high dose and satellite high dose group animals were comparable to their respective control group animals.

Urine samples were collected from all animals in the last week of the experiment. No changes were noted in the urine parameters of any of the treatment group animals when compared to their control counterparts (Appendix: 7).

Ophthalmological examination of all animals was done once prior to the initiation of treatment and thereafter before their scheduled sacrifice. No noteworthy findings were noticed in the animals of low dose (100 mg/kg B.wt.), intermediate dose (500 mg/kg B.wt.), high dose (1000 mg/kg B.wt.) and satellite high dose (1000 mg/kg B.wt.) when compared to their respective control counterparts (Appendix: 8).

Neurobehavioral examination of control and high dose group animals was done before their scheduled sacrifice. No neurological defects were noticed (examined at 30 minutes and 1 hour after dose administration) in the animals of high dose (1000 mg/kg B.wt.) when compared to their respective control counterparts (Appendix: 11).

After the completion of 90 days dosing, all the animals of treatment and control groups were sacrificed. The animals of satellite groups were sacrificed, 28 days after the terminal sacrifice.

All animals from each group were sacrificed and examined for gross pathological findings. A detailed gross pathological examination was carried out. No test item related gross pathological findings were observed. (Appendix: 9).

There were no histopathological changes in the animals of high dose (1000 mg/kg B.wt.) group when compared to its control counterparts (Appendix: 10).

Under the conditions of this study, the repeated oral administration of 'Lentein Complete' in Wistar rats at the dose level of 1000 mg/kg b.wt. daily for 90 days did not induce any observable toxic effects, when compared to its corresponding control group of animals. Hence, may be considered as **"No Observed Adverse Effect Level"**

N.O.A.E.L. ≥1000 mg/kg b.wt

SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH:DELHI

Confidential

STUDY No. : 1704-1-451-1004
TEST ITEM : LENTEIN COMPLETE
STUDY TITLE : REPEATED DOSE (90 DAYS) ORAL TOXICITY STUDY WITH LENTEIN COMPLETE IN WISTAR RATS
REPORT No. :
DATE OF COMPLETION OF STUDY:

1. INTRODUCTION

The purpose of this study was to determine the toxicity of "Lentein Complete" in male and female Wistar rats when administered once daily by oral gavage for 90 consecutive days, and to assess delayed onset of any toxicity or persistence or reversibility of any effects in further 28 days treatment free period.

1.1Study Objectives

a) To assess the toxicological effects of "Lentein Complete" on repeated oral administration for 90 consecutive days in Wistar rats.

b) To obtain the information on toxic effects likely to arise from a repeated oral administration of the test item and to determine the No Observed Adverse Effect Level (NOAEL).

1.2 Testing Guidelines

The Organization for Economic Co-operation and Development (OECD) Guidelines for testing of chemicals, Repeated Dose 90 Days Oral toxicity Study in Rodents (No. 408, Section 4: Health Effects) adopted on 21st September, 1998.

1.3 Test Facility and Study Period

This study was performed at Toxicology Centre, Shriram Institute for Industrial Research, Delhi-110007

Date of initiation of study	:	17.04.2017
Date of initiation of experiment	:	01.05.2017
Dates of initiation of dosing	:	06.05.2017 (Dose range finding) Control male: 22.05.2017 (Main study) High dose male: 22.05.2017 Control female: 23.05.2017 High dose female: 23.05.2017 Low dose male: 24.05.2017 Intermediate dose male: 24.05.2017 Low dose female: 25.05.2017 Intermediate dose female: 25.05.2017 Satellite control: 22.05.2017 Satellite high dose: 22.05.2017
Dates of Necropsy	:	20.08.2017, 21.08.2017, 22.08.2017 23.08.2017, 17.09.2017
Date of completion of experiment	:	10.10.2017
Date of completion of study	:	

1.4 Archiving

On completion of the study; raw data, study plan, study schedule, observation sheets, tissue blocks, specimens, slides together with the copy of final study report and the representative

test item will be retained in the archives of Test Facility 'Toxicology Centre, Shriram Institute for Industrial research, Delhi' for ten years. After completion of archival period sponsor consent will be sought to either extend the archiving period or return the archived material to the sponsor or for the disposal of the material.

2. EXPERIMENTAL PROCEDURE

2.1 Test Item Details

The details of the test item as per the Certificate of Analysis provided by the sponsor:

Name of Test item	Lentein™ Complete		
Common name	Water lentil (*Lemnaceae*) protein		
Plant part	Whole plant		
Family	*Lemnaceae*		
Lot number	CSPBWL 170209		
Date of Manufacture	02/09/2017		
Best used by	02/09/2018		
Test	**Specifications**	**Results**	**Test Methods**
Particle size	D90:<350 microns		Rotap Granulation
Protein dry wt.	45-50%	47%	AOAC 990.03
Dietary fiber dry wt.	35-45%	36%	AOAC 991.43
Fat (AH) dry wt.	<10%	10%	AOAC 922.06
Ash dry wt.	<10%	5%	AOAC 923.03/32.1.05 16TH Ed.
Moisture	<10%	2%	AOCS Ba 2a-38
Heavy Metals: Arsenic Cadmium Lead Mercury	 <0.50 ppm <0.05 ppm <0.20 ppm <0.05 ppm	 0.05 <0.01 0.02 0.012	 AOAC 2013.06 AOAC 2013.06 AOAC 2013.06 AOAC 2013.06
Aerobic plate count	$<10^5$ cfu/g	820	AOAC 966.23
Clostridium perfringens	<100 cfu/g	<10	AOAC 976.30
Coliforms	<100 cfu/g	<10	AOAC 991.14
E.coli	<10 cfu/g	<10	AOAC 991.14
Listeria monocytogenes	Negative/25 g	Neg	AOAC RI 080901
Salmonella	Negative/25 g	Neg	AOAC 2003.09
Yeast	<100 cfu/g	<10	FDA-BAM, Chapter 18
Molds	<100 cfu/g	<10	FDA-BAM, Chapter 18
Storage conditions	Store in original sealed bag with low relative humidity (<60% humidity) and cool temperature (below 25°C/75°F) in dark conditions		
Country of origin	USA		

-Pages 11 to 27 available upon request-

7. REFERENCES

1. OECD Guidelines for Testing of chemicals, Repeated Dose 90 Days Oral toxicity Study in Rodents (No. 408, Section 4: Health effects) adopted on 21st September, 1998.
2. Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), Animal Welfare Division, Ministry of Environment and Forests and Institutional Animal Ethics Committee permission for the use of laboratory animals.

ABBREVIATIONS USED

DLC	-	Diffential Leuococyte count
F	-	Female
M	-	Male
Hb	-	Haemoglobin
HCT	-	Haematocrit
NOAEL	-	No observed adverse effect level
RBC	-	Red blood cell
TP	-	Total protein
WBC	-	White blood cell
GIT	-	Gastro Intestinal Tract
LD	-	Low dose
ID	-	Intermediate dose
HD	-	High dose
MCH	-	Mean corpuscular hemoglobin
MCHC	-	Mean corpuscular hemoglobin concentration

-Pages 29 to 236 available upon request-

2) Acute Oral Toxicity Study with LENTEIN™ Complete

SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH:DELHI

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STUDY REPORT

Study Number : 1709-1-451-953
Study Title : Acute Oral Toxicity Study with "Lentein Complete" in Wistar rats
Test Item : Lentein Complete
Study Director : Dr. Pooja

Sponsor's Name & Address:
M/s Parabel USA Inc.
7898 Headwaters Commerce Street
Fellsmare, FL 32948
USA

Regulatory Guideline:
OECD Guideline for Testing of Chemicals, Acute oral toxicity-Fixed dose procedure (No. 420, Section 4: Health effects) adopted on 17th December 2001

Test Facility's Name & Address:
Toxicology Centre
Shriram Institute for Industrial Research
(A Unit of Shriram Scientific & Industrial Research Foundation)
19, University Road, Delhi – 110007
Email ID: sridlhi@vsnl.com
Tel. 27667267, 27667860, 27667432
Fax No. +91-11-27667676, 27667207

Page 1 of 26

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STUDY NO. : **1709-1-451-953**
TEST ITEM : **LENTEIN COMPLETE**
STUDY TITLE : **ACUTE ORAL TOXICITY STUDY WITH LENTEIN COMPLETE IN WISTAR RATS**
REPORT NO. :
DATE OF COMPLETION OF STUDY:

STATEMENT OF QUALITY ASSURANCE UNIT

Quality Assurance Unit of the testing facility inspected the conduct of study entitled "Acute Oral Toxicity Study with 'Lentein Complete' in Wistar rats" on the following dates:

S. No.	Critical Phases of study	Dates of Inspection	Dates of Reporting	
			Study Director	Management
1.	Study Plan	10.09.2017	10.09.2017	10.09.2017
2.	Study Conduct	16.09.2017	16.09.2017	16.09.2017
3.	Records (Raw data)	07.10.2017	07.10.2017	07.10.2017
4.	Draft Report	23.10.2017	23.10.2017	23.10.2017

This study was conducted in accordance to approved study plan and the Standard Operating Procedures for non-clinical laboratory studies. No findings were noticed during inspection, which would have impaired this study in any way.
Report reflects the raw data of the study.

(b) (6)

Dr. M.L. Aggarwal — Head Quality Assurance Unit | Signature | **24.10.2017** — Date

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STUDY NO. : **1709-1-451-953**
TEST ITEM : **LENTEIN COMPLETE**
STUDY TITLE : **ACUTE ORAL TOXICITY STUDY WITH LENTEIN COMPLETE IN WISTAR RATS**
REPORT NO. :
DATE OF COMPLETION OF STUDY:

STATEMENT OF COMPLIANCE

The study entitled "Acute Oral Toxicity Study with 'Lentein Complete' in Wistar rats" was performed in accordance with standard operating procedures of Toxicology Centre, Shriram Institute for Industrial Research, Delhi as well as the approved study plan.

We hereby attest the authenticity of the study and guarantee that this report represents a true and accurate record of results obtained and shall not be reproduced except in full, without the written approval of the sponsor.

The study was conducted to meet the requirement of OECD Guidelines for Testing of chemicals, Acute oral toxicity Study- Fixed Dose Procedure (No. 420, Section 4: Health effects) adopted on 17th December 2001 for non-clinical laboratory studies.

All original raw data including observation sheet, study plan and a copy of the final report and the representative test item are archived in the archives at Toxicology Centre, Shriram Institute for Industrial Research, Delhi. There were no known circumstances that may have affected the quality or integrity of the study.

The sponsor is responsible for necessary evaluations of the test item concerning the chemical purity, identity, stability and other required data.

	(b) (6)	
Dr. Pooja		**24.10.2017**
Study Director	Signature	Date

	(b) (6)	
Dr. K. M. Chacko		**24.10.2017**
Test Facility Management	Signature	Date

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STUDY NO. : **1709-1-451-953**
TEST ITEM : **LENTEIN COMPLETE**
STUDY TITLE : **ACUTE ORAL TOXICITY STUDY WITH LENTEIN COMPLETE IN WISTAR RATS**
REPORT NO. :
DATE OF COMPLETION OF STUDY:

KEY PERSONNEL INVOLVED IN THE STUDY

DESIGNATION	NAME & ADDRESS
Study Director	**Dr. Pooja, M.Sc., PhD** Toxicology Centre Shriram Institute for Industrial Research 19, University Road, Delhi – 110007 Email ID: sridlhi@vsnl.com Tel. 27667267, 27667860, 27667432 Fax No. 91+11-27667676, 27667207
Study Personnel	**Ms. Deepti, M.Sc.** Toxicology Centre Shriram Institute for Industrial Research 19, University Road, Delhi – 110007 Email ID: sridlhi@vsnl.com Tel. 27667267, 27667860, 27667432 Fax No. 91+11-27667676, 27667207
Study Pathologist	**Dr. B. N. Panda, M.V.Sc.** Toxicology Centre Shriram Institute for Industrial Research 19, University Road, Delhi – 110007 Email ID: sridlhi@vsnl.com Tel. 27667267, 27667860, 27667432 Fax No. 91+11-27667676, 27667207

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STUDY NO. : **1709-1-451-953**
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REPORT NO. :
DATE OF COMPLETION OF STUDY:

INDEX

Continued...

SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH; DELHI

Confidential

STUDY NO. : **1709-1-451-953**
TEST ITEM : **LENTEIN COMPLETE**
STUDY TITLE : **ACUTE ORAL TOXICITY STUDY WITH LENTEIN COMPLETE IN WISTAR RATS**

REPORT NO. :
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SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH; DELHI

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STUDY NO. : **1709-1-451-953**
TEST ITEM : **LENTEIN COMPLETE**
STUDY TITLE : **ACUTE ORAL TOXICITY STUDY WITH LENTEIN COMPLETE IN WISTAR RATS**
REPORT NO. :
DATE OF COMPLETION OF STUDY:

SUMMARY

In the assessment and evaluation of the toxic characteristics of a test item, determination of "Acute Oral Toxicity in Wistar rats" is usually an initial step. This study was hence, performed to assess the Acute Oral Toxicity Study with 'Lentein Complete' in Wistar rats, sponsored by 'Parabel USA Inc.'.

The procedure followed: OECD Guidelines for Testing of Chemicals, Acute Oral Toxicity Study-Fixed Dose Procedure (No. 420, Section 4: Health effects) adopted on 17th December 2001 for non-clinical laboratory studies.

A Sighting Study, at limit dose level of 2000 mg/kg body weight was conducted, by using One female rat, fasted overnight prior to dosing (approximately 16 hours) and till 4 hours after the dosing in the first step. The test item was administered orally by gavage using a cannula.

No toxic signs and symptoms or mortality was noticed in sighting study, hence main study was performed by taking four female rats, which were administered orally with the same dose of 2000 mg/kg body weight.

No mortality or toxic signs and symptoms were observed in any of the animals, at sighting as well as main study. Hence, no further testing was required.

The body weight gain was comparable to each other and found normal.

At the completion of observation period of 14 days, all the animals were sacrificed and subjected to gross pathological examination and did not reveal any pathological changes.

Under the conditions of this study, no toxic signs and symptoms/ mortality was observed in any of the animals at the dose level of 2000 mg/kg b.wt.

Hence, the LD_{50} range of 'Lentein Complete' lies between >2000-5000 mg/kg B.wt. and is categorized as Category 5/ Unclassified as per the Globally Harmonized Classification System (GHS).

LD_{50} Range: > 2000-5000 mg/kg B.wt

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STUDY NO. : **1709-1-451-953**
TEST ITEM : **LENTEIN COMPLETE**
STUDY TITLE : **ACUTE ORAL TOXICITY STUDY WITH LENTEIN COMPLETE IN WISTAR RATS**
REPORT NO. :
DATE OF COMPLETION OF STUDY:

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1. INTRODUCTION

This study was designed to provide information on the acute toxicity of test item in Wistar rats when the test item was administered orally to the animals in a stepwise manner.

1.1 Study Objectives

(a) To determine the acute oral toxicity based on a stepwise procedure using a minimum number of animals at each step to enable the classification of the test item according to 'Globally harmonized system' (GHS).

(b) To determine the range of exposures, where lethality is expected, since death of animal is still the major end point of the test.

(c) This Fixed Dose Procedure provides information for hazard assessment and hazard classification purposes.

1.2 Testing Guidelines

The Organization for Economic Co-operation and Development (OECD) Guidelines for testing of chemicals, Acute oral toxicity Study-Fixed Dose Procedure (No. 420, Section 4: Health Effects) adopted on 17th December, 2001.

1.3 Test Facility and Study Period

This study was performed at the Toxicology Centre, Shriram Institute for Industrial Research, Delhi-110007

Date of initiation of study	:	11.09.2017
Date of initiation of experiment	:	11.09.2017
Date of completion of acclimatization		
Sighting Study	:	15.09.2017
Main Study	:	17.09.2017
Date of initiation of dosing		
Sighting Study	:	16.09.2017
Main Study	:	18.09.2017
Date of completion of experiment	:	02.10.2017
Date of completion of study	:	

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STUDY NO. : **1709-1-451-953**
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DATE OF COMPLETION OF STUDY:

1.4 Archiving

After completion of the study all raw data including study plan, study schedule, observation sheets, Study report and the representative sample of the test item will be archived for 10 years. After the completion of this period sponsor's consent will be sought to either extend the archiving period or return the material to the sponsor or for the disposal of the test item.

2. EXPERIMENTAL PROCEDURE

2.1 Test Item Details

The details of the Test item as per the Certificate of Analysis provided by the sponsor:

Name of Test item	Lentein™ Complete		
Common name	Water lentil (*Lemnaceae*) protein		
Plant part	Whole plant		
Family	*Lemnaceae*		
Lot number	CSPBWL 170209		
Date of Manufacture	02/09/2017		
Best used by	02/09/2018		
Test	**Specifications**	**Results**	**Test Methods**
Particle size	D90:<350 microns		Rotap Granulation
Protein dry wt.	45-50%	47%	AOAC 990.03
Dietary fiber dry wt.	35-45%	36%	AOAC 991.43
Fat (AH) dry wt.	<10%	10%	AOAC 922.06
Ash dry wt.	<10%	5%	AOAC 923.03/32.1.05 16TH Ed.
Moisture	<10%	2%	AOCS Ba 2a-38
Heavy Metals: Arsenic Cadmium Lead Mercury	 <0.50 ppm <0.05 ppm <0.20 ppm <0.05 ppm	 0.05 <0.01 0.02 0.012	 AOAC 2013.06 AOAC 2013.06 AOAC 2013.06 AOAC 2013.06
Aerobic plate count	$<10^5$ cfu/g	820	AOAC 966.23
Clostridium perfringens	<100 cfu/g	<10	AOAC 976.30
Coliforms	<100 cfu/g	<10	AOAC 991.14
E.coli	<10 cfu/g	<10	AOAC 991.14
Listeria monocytogenes	Negative/25 g	Neg	AOAC RI 080901
Salmonella	Negative/25 g	Neg	AOAC 2003.09
Yeast	<100 cfu/g	<10	FDA-BAM, Chapter 18
Molds	<100 cfu/g	<10	FDA-BAM, Chapter 18
Storage conditions	Store in original sealed bag with low relative humidity (<60% humidity) and cool temperature (below 25°C/75°F) in dark conditions		
Country of origin	USA		

-Pages 10-20 are available upon request-

5. CONCLUSION

Under the conditions of this study, all the animals administered with the dose level of 2000 mg/kg body weight did not show any toxic signs and symptoms or mortality.

Hence, the LD_{50} range of 'Lentein Complete' lies between >2000-5000 mg/kg B.wt. and is categorized as Category 5/ Unclassified as per the Globally Harmonized Classification System (GHS).

LD_{50} Range: > 2000-5000 mg/kg B.wt

The study has been conducted as per 'OECD Guidelines for Testing of chemicals, Acute oral toxicity Study- Fixed Dose Procedure (No. 420, Section 4: Health effects) adopted on 17th December 2001 for non-clinical laboratory studies.

6. REFERENCES

1. OECD Guidelines for Testing of chemicals, Acute oral toxicity Study- Fixed Dose Procedure (No. 420, Section 4: Health effects) adopted on 17th December 2001.

2. Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), Animal Welfare Division, Ministry of Environment and Forests and Institutional Animal Ethics Committee permission for the use of laboratory animals.

-Pages 21 to 26 available upon request-