

**TABLE 8: SUMMARY OF MEAN DAILY DIETARY INTAKE OF  
SOY LEGHEMOGLOBIN PREPARATION<sup>1</sup>**

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<sup>1</sup> Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Dietary Intake Variable (mg/kg/day)

Sex: Male		0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date					
0 → 7	Mean	0.0	485.4	966.5	1459.8
	SD	0.0	20.9	42.5	103.0
	N	10	10	10	10
7 → 14	Mean	0.0	540.5	1095.9	1631.5
	SD	0.0	24.5	53.5	78.9
	N	10	10	10	10
14 → 21	Mean	0.0	503.2	1007.2	1513.7
	SD	0.0	30.7	61.7	81.1
	N	10	10	10	10
21 → 28	Mean	0.0	495.9	973.0	1473.9
	SD	0.0	33.2	49.1	92.5
	N	10	10	10	10
0 → 28	Mean	0.0	478.9	954.7	1438.2
	SD	0.0	24.7	36.0	78.6
	N	10	10	10	10

Sex: Female		0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date					
0 → 7	Mean	0.0	498.0	995.9	1481.1
	SD	0.0	43.5	29.2	115.0
	N	10	10	10	10
7 → 14	Mean	0.0	541.9	1064.6	1604.6
	SD	0.0	49.9	39.2	116.7
	N	10	10	10	10
14 → 21	Mean	0.0	518.8	1015.1	1537.2
	SD	0.0	53.9	34.3	92.3
	N	10	10	10	10
21 → 28	Mean	0.0	482.4	994.0	1460.2
	SD	0.0	41.9	56.0	79.0
	N	10	10	10	10
0 → 28	Mean	0.0	497.8	983.4	1470.4
	SD	0.0	42.8	29.0	88.2
	N	10	10	10	10

**TABLE 9: SUMMARY OF HEMATOLOGY VALUES<sup>1</sup>**

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<sup>1</sup> Individual data are reported in the Clinical Pathology Report presented in Appendix N.

Sex: Male			0 mg/kg/day Group 1	250 mg/kg/day Group 2	500 mg/kg/day Group 3	750 mg/kg/day Group 4
Day(s) Relative to Start Date						
RBC (x10 <sup>6</sup> /μL)	22	Mean	7.72	7.60	7.61	7.70
		SD	0.23	0.34	0.35	0.27
		N	10	10	10	10
		%Diff		-1.6	-1.5	-0.3
HGB (g/dL)	22	Mean	15.6	15.4	15.5	15.9
		SD	0.3	0.6	0.6	0.4
		N	10	10	10	10
		%Diff		-1.5	-1.0	1.4
HCT (%)	22	Mean	45.5	45.1	45.1	45.9
		SD	0.9	1.5	1.7	0.8
		N	10	10	10	10
		%Diff		-0.9	-0.8	1.0
MCV (fL)	22	Mean	58.9	59.3	59.3	59.7
		SD	1.0	2.3	1.5	1.9
		N	10	10	10	10
		%Diff		0.7	0.7	1.3
MCH (pg)	22	Mean	20.3	20.3	20.4	20.6
		SD	0.5	0.9	0.5	0.7
		N	10	10	10	10
		%Diff		0.2	0.6	1.6
MCHC (g/dL)	22	Mean	34.4	34.2	34.4	34.5
		SD	0.4	0.4	0.3	0.5
		N	10	10	10	10
		%Diff		-0.5	-0.1	0.4
RDW (%)	22	Mean	12.1	12.5	12.5	12.3
		SD	0.3	0.5	0.3	0.5
		N	10	10	10	10
		%Diff		3.0	3.3	1.6
PLT (x10 <sup>3</sup> /μL)	22	Mean	1160	1202	1171	1227
		SD	121	69	76	185
		N	10	10	10	10
		%Diff		3.6	1.0	5.8

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation :Automatic]

Sex: Male			0 mg/kg/day Group 1	250 mg/kg/day Group 2	500 mg/kg/day Group 3	750 mg/kg/day Group 4
Day(s) Relative to Start Date						
WBC (x10 <sup>3</sup> /μL)	22	Mean	13.00	14.41	11.13	13.45
		SD	1.33	2.67	1.82	4.41
		N	10	10	10	10
		%Diff		10.8	-14.4	3.4
ANEU (x10 <sup>3</sup> /μL)	22	Mean	1.91	1.99	1.75	1.57
		SD	0.67	0.43	0.43	0.62
		N	10	10	10	10
		%Diff		4.1	-8.1	-17.8
ALYM (x10 <sup>3</sup> /μL)	22	Mean	10.49	11.79	8.86	11.29
		SD	1.17	2.48	1.70	4.15
		N	10	10	10	10
		%Diff		12.4	-15.5	7.7
AMON (x10 <sup>3</sup> /μL)	22	Mean	0.31	0.34	0.28	0.30
		SD	0.10	0.11	0.05	0.10
		N	10	10	10	10
		%Diff		10.2	-9.8	-1.5
AEOS (x10 <sup>3</sup> /μL)	22	Mean	0.12	0.13	0.11	0.11
		SD	0.04	0.08	0.04	0.05
		N	10	10	10	10
		%Diff		4.4	-7.2	-7.6
ABAS (x10 <sup>3</sup> /μL)	22	Mean	0.09	0.09	0.07	0.10
		SD	0.03	0.04	0.02	0.06
		N	10	10	10	10
		%Diff		-5.0	-27.0	6.2
ALUC (x10 <sup>3</sup> /μL)	22	Mean	0.08	0.08	0.06	0.08
		SD	0.03	0.03	0.02	0.04
		N	10	10	10	10
		%Diff		-8.1	-27.0	-2.4
ARET (x10 <sup>3</sup> /μL)	22	Mean	232.6	235.8	246.3	243.8
		SD	31.2	40.7	24.1	41.1
		N	10	10	10	10
		%Diff		1.4	5.9	4.8

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation :Automatic]

Sex: Female			0 mg/kg/day Group 1	250 mg/kg/day Group 2	500 mg/kg/day Group 3	750 mg/kg/day Group 4
Day(s) Relative to Start Date						
RBC (x10 <sup>6</sup> /μL)	22	Mean	7.59	8.01 # <sup>1</sup>	7.86	7.63
		SD	0.24	0.38	0.24	0.30
		N	10	10	10	10
		%Diff		5.6	3.6	0.6
HGB (g/dL)	22	Mean	15.3	16.2 # <sup>1</sup>	15.7	15.5
		SD	0.5	0.5	0.4	0.6
		N	10	10	10	10
		%Diff		5.7	2.5	0.9
HCT (%)	22	Mean	43.6	45.9 # <sup>1</sup>	44.7	44.0
		SD	1.2	1.2	1.3	1.7
		N	10	10	10	10
		%Diff		5.2	2.4	0.9
MCV (fL)	22	Mean	57.5	57.4	56.8	57.7
		SD	1.1	2.2	1.2	2.2
		N	10	10	10	10
		%Diff		-0.2	-1.1	0.4
MCH (pg)	22	Mean	20.2	20.2	20.0	20.3
		SD	0.3	0.7	0.5	0.7
		N	10	10	10	10
		%Diff		0.1	-1.0	0.3
MCHC (g/dL)	22	Mean	35.2	35.3	35.2	35.2
		SD	0.7	0.3	0.4	0.5
		N	10	10	10	10
		%Diff		0.3	0.1	0.0
RDW (%)	22	Mean	11.3	11.3	11.2	11.5
		SD	0.4	0.5	0.3	0.5
		N	10	10	10	10
		%Diff		0.1	-0.4	1.7
PLT (x10 <sup>3</sup> /μL)	22	Mean	1190	1176	1230	1229
		SD	108	127	115	114
		N	10	10	10	10
		%Diff		-1.1	3.4	3.3

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation :Automatic]  
1 [#- Test: Dunnett 2 Sided p < 0.05]

Sex: Female			0 mg/kg/day Group 1	250 mg/kg/day Group 2	500 mg/kg/day Group 3	750 mg/kg/day Group 4
Day(s) Relative to Start Date						
WBC (x10 <sup>3</sup> /μL)	22	Mean	10.08	11.87	11.59	10.19
		SD	1.70	1.75	3.35	3.72
		N	10	10	10	10
		%Diff		17.7	15.0	1.1
ANEU (x10 <sup>3</sup> /μL)	22	Mean	1.48	1.56	1.68	1.54
		SD	0.30	0.58	0.85	1.10
		N	10	10	10	10
		%Diff		5.3	13.9	4.0
ALYM (x10 <sup>3</sup> /μL)	22	Mean	8.15	9.74	9.29	8.21
		SD	1.58	1.43	2.71	2.88
		N	10	10	10	10
		%Diff		19.5	14.0	0.7
AMON (x10 <sup>3</sup> /μL)	22	Mean	0.25	0.29	0.33	0.22
		SD	0.15	0.06	0.15	0.14
		N	10	10	10	10
		%Diff		16.7	32.5	-11.1
AEOS (x10 <sup>3</sup> /μL)	22	Mean	0.11	0.13	0.15	0.12
		SD	0.03	0.04	0.05	0.06
		N	10	10	10	10
		%Diff		21.4	35.8	9.0
ABAS (x10 <sup>3</sup> /μL)	22	Mean	0.04	0.07 # <sup>1</sup>	0.06	0.05
		SD	0.01	0.03	0.03	0.04
		N	10	10	10	10
		%Diff		93.2	64.1	46.7
ALUC (x10 <sup>3</sup> /μL)	22	Mean	0.05	0.07	0.07	0.05
		SD	0.02	0.02	0.03	0.04
		N	10	10	10	10
		%Diff		29.1	26.2	2.9
ARET (x10 <sup>3</sup> /μL)	22	Mean	205.8	182.4	169.1 # <sup>1</sup>	184.2
		SD	33.9	32.9	30.9	33.7
		N	10	10	10	10
		%Diff		-11.3	-17.8	-10.5

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation :Automatic]

1 [# - Test: Dunnett 2 Sided p < 0.05]



**TABLE 10: SUMMARY OF COAGULATION VALUES<sup>1</sup>**

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<sup>1</sup> Individual data are reported in the Clinical Pathology Report presented in Appendix N.

Sex: Male			0 mg/kg/day Group 1	250 mg/kg/day Group 2	500 mg/kg/day Group 3	750 mg/kg/day Group 4
Day(s) Relative to Start Date						
PT (sec)	29	Mean	10.7	10.7	10.6	10.6
		SD	0.3	0.4	0.2	0.2
		N	10	10	10	10
APTT (sec)	29	Mean	20.2	23.8	24.9 @ <sup>1</sup>	23.9 @ <sup>1</sup>
		SD	2.4	5.3	6.9	4.8
		N	10	10	10	10

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation :Automatic]  
1 [@ - Test: Dunnett Non-Parametric 2 Sided p < 0.05]

Sex: Female			0 mg/kg/day Group 1	250 mg/kg/day Group 2	500 mg/kg/day Group 3	750 mg/kg/day Group 4
Day(s) Relative to Start Date						
PT (sec)	30	Mean	10.0	9.8	10.0	9.8
		SD	0.2	0.2	0.3	0.2
		N	10	10	10	10
APTT (sec)	30	Mean	21.9	20.0	20.8	19.4
		SD	2.5	3.1	5.0	1.9
		N	10	10	10	10

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation :Automatic]

**TABLE 11: SUMMARY OF CLINICAL CHEMISTRY VALUES<sup>1</sup>**

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<sup>1</sup> Individual data are reported in the Clinical Pathology Report presented in Appendix N.

Sex: Male			0 mg/kg/day Group 1	250 mg/kg/day Group 2	500 mg/kg/day Group 3	750 mg/kg/day Group 4
Day(s) Relative to Start Date						
AST (U/L)	22	Mean	73	76	79	78
		SD	8	9	7	8
		N	5	9	6	8
		%Diff		4.0	7.5	6.9
ALT (U/L)	22	Mean	29	28	28	30
		SD	4	4	3	4
		N	10	10	10	10
		%Diff		-3.1	-2.4	2.4
SDH (U/L)	22	Mean	8.2	8.1	8.4	8.0
		SD	1.4	1.7	2.4	1.4
		N	5	9	6	8
		%Diff		-0.8	2.7	-1.9
ALKP (U/L)	22	Mean	183	216	216	205
		SD	24	29	44	42
		N	10	10	10	10
		%Diff		18.6	18.5	12.3
BILI (mg/dL)	22	Mean	0.17	0.17	0.18	0.18
		SD	0.02	0.02	0.02	0.02
		N	10	10	10	10
		%Diff		1.2	4.1	5.9
BUN (mg/dL)	22	Mean	10	11	10	11
		SD	1	1	1	2
		N	10	10	10	10
		%Diff		4.8	-3.8	1.0
CREA (mg/dL)	22	Mean	0.22	0.23	0.23	0.21
		SD	0.01	0.02	0.02	0.02
		N	10	10	10	10
		%Diff		3.6	4.1	-5.9
CHOL (mg/dL)	22	Mean	76	73	72	67
		SD	16	27	14	12
		N	10	10	10	10
		%Diff		-3.4	-5.4	-11.7

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation :Automatic]

Sex: Male			0 mg/kg/day Group 1	250 mg/kg/day Group 2	500 mg/kg/day Group 3	750 mg/kg/day Group 4
Day(s) Relative to Start Date						
TRIG (mg/dL)	22	Mean	66	67	67	68
		SD	17	13	17	26
		N	10	10	10	10
		%Diff		1.8	0.9	2.4
GLUC (mg/dL)	22	Mean	95	100	102	98
		SD	12	9	13	8
		N	10	10	10	10
		%Diff		5.4	7.1	2.6
TP (g/dL)	22	Mean	6.0	6.1	6.2	6.0
		SD	0.2	0.2	0.2	0.2
		N	10	10	10	10
		%Diff		0.7	2.8	0.2
ALB (g/dL)	22	Mean	3.1	3.2	3.3 # <sup>1</sup>	3.2
		SD	0.1	0.1	0.1	0.1
		N	10	10	10	10
		%Diff		2.2	4.1	1.9
GLOB (g/dL)	22	Mean	2.9	2.8	2.9	2.8
		SD	0.1	0.2	0.1	0.2
		N	10	10	10	10
		%Diff		-1.0	1.4	-1.7
CALC (mg/dL)	22	Mean	10.4	10.4	10.4	10.5
		SD	0.2	0.2	0.2	0.2
		N	10	10	10	10
		%Diff		-0.1	0.1	0.8
IPHS (mg/dL)	22	Mean	8.6	8.7	8.8	8.6
		SD	0.4	0.4	0.9	0.4
		N	5	9	6	8
		%Diff		0.6	2.1	-0.3
NA (mmol/L)	22	Mean	140.5	142.1	141.1	141.7
		SD	4.2	0.6	0.7	0.8
		N	10	10	10	10
		%Diff		1.1	0.4	0.9

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation :Automatic]  
1 [#- Test: Dunnett 2 Sided p < 0.05]

Sex: Male			0 mg/kg/day Group 1	250 mg/kg/day Group 2	500 mg/kg/day Group 3	750 mg/kg/day Group 4
Day(s) Relative to Start Date						
K (mmol/L)	22	Mean	5.03	5.19	5.55 # <sup>1</sup>	5.10
		SD	0.25	0.26	0.61	0.25
		N	10	10	10	10
		%Diff	.	3.1	10.4	1.4
CL (mmol/L)	22	Mean	100.8	102.0	101.6	101.7
		SD	2.4	1.0	0.8	1.2
		N	10	10	10	10
		%Diff	.	1.2	0.8	0.9

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation :Automatic]  
1 [#- Test: Dunnett 2 Sided p < 0.05]

Sex: Female			0 mg/kg/day Group 1	250 mg/kg/day Group 2	500 mg/kg/day Group 3	750 mg/kg/day Group 4
Day(s) Relative to Start Date						
AST (U/L)	22	Mean	69	69	64	65
		SD	6	10	8	6
		N	9	9	10	10
		%Diff	.	-0.3	-7.4	-6.5
ALT (U/L)	22	Mean	25	26	25	27
		SD	4	5	6	5
		N	10	10	10	10
		%Diff	.	2.8	-0.4	5.2
SDH (U/L)	22	Mean	8.7	8.1	8.0	9.9
		SD	2.2	1.2	0.9	2.5
		N	9	9	10	10
		%Diff	.	-7.4	-9.0	12.9
ALKP (U/L)	22	Mean	137	107 # <sup>1</sup>	121	108 # <sup>1</sup>
		SD	16	19	29	25
		N	10	10	10	10
		%Diff	.	-22.4	-12.1	-21.3
BILI (mg/dL)	22	Mean	0.18	0.19	0.20	0.19
		SD	0.02	0.02	0.02	0.03
		N	10	10	10	10
		%Diff	.	8.4	10.6	7.8
BUN (mg/dL)	22	Mean	12	11	12	12
		SD	2	1	2	1
		N	10	10	10	10
		%Diff	.	-11.5	-0.8	0.0
CREA (mg/dL)	22	Mean	0.28	0.26	0.27	0.28
		SD	0.02	0.02	0.03	0.03
		N	10	10	10	10
		%Diff	.	-6.9	-2.9	1.1
CHOL (mg/dL)	22	Mean	85	95	98	94
		SD	11	19	19	22
		N	10	10	10	10
		%Diff	.	12.2	15.6	11.2

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation :Automatic]  
1 [#- Test: Dunnett 2 Sided p < 0.05]



Sex: Female			0 mg/kg/day Group 1	250 mg/kg/day Group 2	500 mg/kg/day Group 3	750 mg/kg/day Group 4
Day(s) Relative to Start Date						
TRIG (mg/dL)	22	Mean	37	38	46	35
		SD	6	9	15	8
		N	10	10	10	10
		%Diff		3.5	24.9	-4.3
GLUC (mg/dL)	22	Mean	118	103 # <sup>1</sup>	104 # <sup>1</sup>	110
		SD	15	10	10	14
		N	10	10	10	10
		%Diff		-13.3	-12.0	-6.7
TP (g/dL)	22	Mean	6.4	6.7	6.8	6.7
		SD	0.3	0.4	0.3	0.4
		N	10	10	10	10
		%Diff		5.1	5.6	3.7
ALB (g/dL)	22	Mean	3.5	3.7	3.7	3.6
		SD	0.2	0.2	0.2	0.3
		N	10	10	10	10
		%Diff		4.0	4.6	3.4
GLOB (g/dL)	22	Mean	2.9	3.1	3.1 # <sup>1</sup>	3.0
		SD	0.1	0.2	0.2	0.1
		N	10	10	10	10
		%Diff		6.6	6.9	4.1
CALC (mg/dL)	22	Mean	10.5	10.9 # <sup>1</sup>	11.0 # <sup>1</sup>	10.7
		SD	0.3	0.3	0.3	0.4
		N	10	10	10	10
		%Diff		3.8	5.1	1.8
IPHS (mg/dL)	22	Mean	7.1	7.8	7.6	7.1
		SD	0.5	0.6	0.4	0.8
		N	9	9	10	10
		%Diff		9.7	6.5	-0.6
NA (mmol/L)	22	Mean	140.3	140.6	140.3	140.2
		SD	1.1	0.6	0.7	1.1
		N	10	10	10	10
		%Diff		0.2	0.0	0.0

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation :Automatic]  
1 [# - Test: Dunnett 2 Sided p < 0.05]

Sex: Female			0 mg/kg/day Group 1	250 mg/kg/day Group 2	500 mg/kg/day Group 3	750 mg/kg/day Group 4
Day(s) Relative to Start Date						
K (mmol/L)	22	Mean	4.56	4.63	4.72	4.74
		SD	0.33	0.38	0.21	0.38
		N	10	10	10	10
		%Diff	.	1.5	3.5	4.0
CL (mmol/L)	22	Mean	102.6	101.3 # <sup>1</sup>	101.1 # <sup>1</sup>	102.1
		SD	1.2	1.4	1.0	1.1
		N	10	10	10	10
		%Diff	.	-1.3	-1.5	-0.5

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation :Automatic]  
1 [#- Test: Dunnett 2 Sided p < 0.05]

**TABLE 12: SUMMARY OF URINALYSIS VALUES<sup>1</sup>**

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<sup>1</sup> Individual data are reported in the Clinical Pathology Report presented in Appendix N.

Sex: Male			0 mg/kg/day Group 1	250 mg/kg/day Group 2	500 mg/kg/day Group 3	750 mg/kg/day Group 4
Day(s) Relative to Start Date						
UVOL (mL)	22	Mean	11.7	11.5	12.3	14.3
		SD	8.2	9.8	7.3	7.7
		N	10	10	10	10
		%Diff		-1.8	4.8	22.0
pH	22	Mean	6.5	6.5	6.6	6.6
		SD	0.3	0.4	0.4	0.4
		N	10	9	10	10
		%Diff		0.0	0.8	1.5
SG	22	Mean	1.027	1.027	1.026	1.024
		SD	0.019	0.015	0.015	0.019
		N	10	9	10	10
		%Diff		0.0	-0.1	-0.3
URO (EU/dL)	22	Mean	0.3	0.2	0.3	0.2
		SD	0.3	0.0	0.3	0.0
		N	10	9	10	10
		%Diff		-28.6	0.0	-28.6
UMTP (mg/dL)	22	Mean	104	241	124	111
		SD	49	365	80	97
		N	10	10	10	10
		%Diff		132.5	19.5	7.4

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation :Automatic]

Sex: Female			0 mg/kg/day Group 1	250 mg/kg/day Group 2	500 mg/kg/day Group 3	750 mg/kg/day Group 4
Day(s) Relative to Start Date						
UVOL (mL)	22	Mean	7.8	6.8	6.5	6.6
		SD	6.4	5.1	3.0	4.1
		N	10	10	10	10
		%Diff		-12.3	-15.9	-14.9
pH	22	Mean	6.4	6.2	6.6	6.5
		SD	0.4	0.4	0.6	0.6
		N	10	10	10	10
		%Diff		-3.9	3.1	0.8
SG	22	Mean	1.037	1.035	1.028	1.030
		SD	0.027	0.023	0.011	0.013
		N	10	10	10	10
		%Diff		-0.2	-0.8	-0.6
URO (EU/dL)	22	Mean	0.2	0.2	0.2	0.3
		SD	0.0	0.0	0.0	0.3
		N	10	10	10	10
		%Diff		0.0	0.0	40.0
UMTP (mg/dL)	22	Mean	43	41	34	44
		SD	34	25	12	30
		N	10	10	10	10
		%Diff		-3.7	-20.0	3.5

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation :Automatic]

**TABLE 13: SUMMARY OF GROSS NECROPSY OBSERVATIONS<sup>1</sup>**

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<sup>1</sup> Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Removal Reason ALL	Male				Female			
	0	512	1024	1536	0	512	1024	1536
	mg/kg/day Group 1	mg/kg/day Group 2	mg/kg/day Group 3	mg/kg/day Group 4	mg/kg/day Group 1	mg/kg/day Group 2	mg/kg/day Group 3	mg/kg/day Group 4
Number of Animals	10	10	10	10	10	10	10	10
Number of Completed Animals	10	10	10	10	10	10	10	10
<b>spleen</b>								
Submitted	10	10	10	10	10	10	10	10
structure							1	
<b>testes-combined</b>								
Submitted	10	10	10	10				
right small soft	1							
<b>uterus</b>								
Submitted					10	10	10	10
fluid filled					4		1	
<b>epididymides-combined</b>								
Submitted	10	10	10	10				
right small	1							

**TABLE 14: SUMMARY OF MEAN TERMINAL BODY AND ORGAN WEIGHTS<sup>1</sup>**

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<sup>1</sup> Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.



Sex: Male			0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date						
Terminal BW (g)	-	Mean	367.5	372.5	384.0	379.3
		SD	25.3	23.8	33.4	21.4
		N	10	10	10	10
Adrenal Glands Wt (g)	-	Mean	0.0654 <sup>1</sup>	0.0655	0.0593	0.0672
		SD	0.0058	0.0112	0.0116	0.0098
		N	10	10	10	10
Brain Wt (g)	-	Mean	2.141 <sup>1</sup>	2.143	2.186	2.152
		SD	0.095	0.110	0.140	0.105
		N	10	10	10	10
Epididymides Wt (g)	-	Mean	1.032 <sup>1</sup>	1.088	1.035	1.008
		SD	0.123	0.083	0.131	0.100
		N	10	10	10	10
Heart Wt (g)	-	Mean	1.195 <sup>1</sup>	1.254	1.272	1.219
		SD	0.104	0.121	0.113	0.088
		N	10	10	10	10
Kidneys Wt (g)	-	Mean	2.641 <sup>1</sup>	2.678	2.789	2.800
		SD	0.297	0.219	0.246	0.241
		N	10	10	10	10
Liver Wt (g)	-	Mean	11.218 <sup>1</sup>	11.182	12.317	12.093
		SD	1.657	0.691	1.804	1.452
		N	10	10	10	10
Spleen Wt (g)	-	Mean	0.831 <sup>1</sup>	0.813	0.769	0.809
		SD	0.125	0.107	0.053	0.105
		N	10	10	10	10
Testes Wt (g)	-	Mean	3.148 <sup>2</sup>	3.381	3.266	3.272
		SD	0.531	0.292	0.251	0.246
		N	10	10	10	10
Thymus Wt (g)	-	Mean	0.5205 <sup>1</sup>	0.5661	0.5466	0.5276
		SD	0.1595	0.1162	0.1185	0.1097
		N	10	10	10	10

1 [I - Automatic Transformation: Identity (No Transformation)]

2 [R - Automatic Transformation: Rank]

Sex: Female			0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date						
Terminal BW (g)	-	Mean	229.2	225.6	236.3	233.8
		SD	22.3	22.7	14.5	11.9
		N	10	10	10	10
Adrenal Glands Wt (g)	-	Mean	0.0717 <sup>1</sup>	0.0713	0.0664	0.0737
		SD	0.0067	0.0089	0.0092	0.0093
		N	10	10	10	10
Brain Wt (g)	-	Mean	2.007 <sup>1</sup>	1.976	2.046	2.021
		SD	0.093	0.099	0.077	0.049
		N	10	10	10	10
Heart Wt (g)	-	Mean	0.840 <sup>1</sup>	0.830	0.850	0.848
		SD	0.092	0.057	0.034	0.065
		N	10	10	10	10
Kidneys Wt (g)	-	Mean	1.752 <sup>1</sup>	1.820	1.769	1.815
		SD	0.164	0.177	0.140	0.101
		N	10	10	10	10
Liver Wt (g)	-	Mean	7.156 <sup>1</sup>	7.636	7.338	7.763
		SD	0.720	1.037	0.512	0.548
		N	10	10	10	10
Ovaries with Oviducts Wt (g)	-	Mean	0.1309 <sup>1</sup>	0.1272	0.1231	0.1364
		SD	0.0173	0.0172	0.0143	0.0150
		N	10	10	10	10
Spleen Wt (g)	-	Mean	0.498 <sup>1</sup>	0.518	0.507	0.513
		SD	0.088	0.119	0.068	0.060
		N	10	10	10	10
Thymus Wt (g)	-	Mean	0.4343 <sup>1</sup>	0.4654	0.4762	0.5218
		SD	0.0998	0.0741	0.0967	0.1127
		N	10	10	10	10
Uterus Wt (g)	-	Mean	0.727 <sup>2</sup>	0.457 <sup>3</sup>	0.615	0.490 <sup>4</sup>
		SD	0.247	0.061	0.276	0.057
		N	10	10	10	10

1 [I - Automatic Transformation: Identity (No Transformation)]

2 [R - Automatic Transformation: Rank]

3 [dd - Test: Dunn 2 Sided p < 0.01]

4 [d - Test: Dunn 2 Sided p < 0.05]

**TABLE 15: SUMMARY OF MEAN ORGAN-TO-BODY WEIGHT RATIOS<sup>1</sup>**

---

<sup>1</sup> Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Sex: Male			0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date						
Adrenal /TBW (Ratio)	-	Mean	0.1781 <sup>1</sup>	0.1766	0.1540	0.1773
		SD	0.0165	0.0328	0.0253	0.0264
		N	10	10	10	10
Brain /TBW (Ratio)	-	Mean	5.846 <sup>1</sup>	5.766	5.722	5.682
		SD	0.411	0.355	0.497	0.294
		N	10	10	10	10
Epididymides /TBW (Ratio)	-	Mean	2.8075 <sup>1</sup>	2.9351	2.7030	2.6712
		SD	0.2682	0.3125	0.3143	0.3544
		N	10	10	10	10
Heart /TBW (Ratio)	-	Mean	3.251 <sup>1</sup>	3.362	3.315	3.214
		SD	0.151	0.151	0.128	0.149
		N	10	10	10	10
Kidneys /TBW (Ratio)	-	Mean	7.184 <sup>1</sup>	7.199	7.274	7.387
		SD	0.610	0.541	0.421	0.560
		N	10	10	10	10
Liver /TBW (Ratio)	-	Mean	30.549 <sup>R<sup>2</sup></sup>	30.052	31.962	31.893
		SD	4.348	1.405	2.654	3.559
		N	10	10	10	10
Spleen /TBW (Ratio)	-	Mean	2.256 <sup>1</sup>	2.199	2.012	2.139
		SD	0.255	0.391	0.184	0.312
		N	10	10	10	10
Testes /TBW (Ratio)	-	Mean	8.549 <sup>1</sup>	9.108	8.564	8.657
		SD	1.201	0.971	0.970	0.885
		N	10	10	10	10
Thymus /TBW (Ratio)	-	Mean	1.4134 <sup>1</sup>	1.5209	1.4171	1.3939
		SD	0.4037	0.3105	0.2319	0.2919
		N	10	10	10	10

1 [ - Automatic Transformation: Identity (No Transformation)]  
2 [R - Automatic Transformation: Rank]

Sex: Female			0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date						
Adrenal /TBW (Ratio)	-	Mean	0.3139 <sup>1</sup>	0.3168	0.2812	0.3157
		SD	0.0265	0.0336	0.0372	0.0389
		N	10	10	10	10
Brain /TBW (Ratio)	-	Mean	8.801 <sup>1</sup>	8.828	8.692	8.664
		SD	0.545	0.852	0.686	0.492
		N	10	10	10	10
Heart /TBW (Ratio)	-	Mean	3.685 <sup>1</sup>	3.692	3.605	3.625
		SD	0.189	0.171	0.178	0.163
		N	10	10	10	10
Kidneys /TBW (Ratio)	-	Mean	7.657 <sup>1</sup>	8.094	7.505	7.783
		SD	0.412	0.639	0.657	0.602
		N	10	10	10	10
Liver /TBW (Ratio)	-	Mean	31.278 <sup>1</sup>	33.819	31.158	33.269
		SD	2.212	2.683	2.883	2.772
		N	10	10	10	10
Ovaries with oviducts/TBW (Ratio)	-	Mean	0.5727 <sup>1</sup>	0.5635	0.5222	0.5835
		SD	0.0669	0.0474	0.0643	0.0581
		N	10	10	10	10
Spleen /TBW (Ratio)	-	Mean	2.171 <sup>1</sup>	2.284	2.149	2.191
		SD	0.300	0.384	0.291	0.206
		N	10	10	10	10
Thymus /TBW (Ratio)	-	Mean	1.8863 <sup>1</sup>	2.0742	2.0184	2.2362
		SD	0.3463	0.3287	0.4057	0.4918
		N	10	10	10	10
Uterus /TBW (Ratio)	-	Mean	3.159 <sup>2</sup>	2.060 <sup>DD</sup>	2.579	2.103 <sup>DD</sup>
		SD	0.949	0.452	1.063	0.277
		N	10	10	10	10

1 [ - Automatic Transformation: Identity (No Transformation)]  
2 [L,AA - Automatic Transformation: Log, (All Groups) Test: Analysis of Variance p < 0.01]  
3 [DD - Test: Dunnett 2 Sided p < 0.01]

**TABLE 16: SUMMARY OF MEAN ORGAN-TO-BRAIN WEIGHT RATIOS<sup>1</sup>**

---

<sup>1</sup> Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Sex: Male			0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date						
Adrenal /BrW (Ratio)	-	Mean	0.0306 <sup>1</sup>	0.0307	0.0270	0.0312
		SD	0.0031	0.0056	0.0043	0.0039
		N	10	10	10	10
Epididymides /BrW (Ratio)	-	Mean	0.4813 <sup>1</sup>	0.5095	0.4738	0.4700
		SD	0.0465	0.0535	0.0521	0.0573
		N	10	10	10	10
Heart /BrW (Ratio)	-	Mean	0.558 <sup>2</sup>	0.585	0.583	0.566
		SD	0.038	0.048	0.052	0.027
		N	10	10	10	10
Kidneys /BrW (Ratio)	-	Mean	1.232 <sup>1</sup>	1.251	1.278	1.300
		SD	0.114	0.100	0.114	0.078
		N	10	10	10	10
Liver /BrW (Ratio)	-	Mean	5.238 <sup>1</sup>	5.228	5.633	5.614
		SD	0.727	0.374	0.740	0.579
		N	10	10	10	10
Spleen /BrW (Ratio)	-	Mean	0.388 <sup>1</sup>	0.380	0.353	0.376
		SD	0.057	0.055	0.039	0.044
		N	10	10	10	10
Testes /BrW (Ratio)	-	Mean	1.469 <sup>1</sup>	1.581	1.498	1.523
		SD	0.235	0.155	0.123	0.125
		N	10	10	10	10
Thymus /BrW (Ratio)	-	Mean	0.2436 <sup>1</sup>	0.2630	0.2502	0.2450
		SD	0.0739	0.0472	0.0514	0.0476
		N	10	10	10	10

1 [I - Automatic Transformation: Identity (No Transformation)]

2 [R - Automatic Transformation: Rank]

Sex: Female			0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date						
Adrenal /BrW (Ratio)	-	Mean	0.0357 <sup>1</sup>	0.0361	0.0325	0.0365
		SD	0.0024	0.0043	0.0047	0.0050
		N	10	10	10	10
Heart /BrW (Ratio)	-	Mean	0.418 <sup>1</sup>	0.420	0.416	0.420
		SD	0.031	0.028	0.026	0.036
		N	10	10	10	10
Kidneys /BrW (Ratio)	-	Mean	0.872 <sup>1</sup>	0.920	0.866	0.898
		SD	0.056	0.082	0.080	0.049
		N	10	10	10	10
Liver /BrW (Ratio)	-	Mean	3.566 <sup>1</sup>	3.862	3.592	3.842
		SD	0.325	0.476	0.310	0.267
		N	10	10	10	10
Ovaries with oviducts/BrW (Ratio)	-	Mean	0.0652 <sup>1</sup>	0.0844	0.0803	0.0676
		SD	0.0075	0.0086	0.0079	0.0078
		N	10	10	10	10
Spleen /BrW (Ratio)	-	Mean	0.248 <sup>1</sup>	0.261	0.248	0.254
		SD	0.039	0.054	0.035	0.031
		N	10	10	10	10
Thymus /BrW (Ratio)	-	Mean	0.2158 <sup>1</sup>	0.2366	0.2332	0.2583
		SD	0.0459	0.0434	0.0489	0.0561
		N	10	10	10	10
Uterus /BrW (Ratio)	-	Mean	0.361 <sup>2</sup>	0.232 <sup>3</sup>	0.301	0.242 <sup>4</sup>
		SD	0.118	0.033	0.136	0.028
		N	10	10	10	10

1 [I - Automatic Transformation: Identity (No Transformation)]

2 [R - Automatic Transformation: Rank]

3 [dd - Test: Dunn 2 Sided p < 0.01]

4 [d - Test: Dunn 2 Sided p < 0.05]



## **APPENDIX A: PROTOCOL AND PROTOCOL AMENDMENTS**

### **PRODUCT IDENTIFICATION**

Soy Leghemoglobin Preparation

**Product Safety Labs**

28-Day dietary Study in rats  
Protocol # P703.01 IMP  
PSL ID: 160720-5R  
Study No: 43166

---

**SOY LEGHEMOGLOBIN PREPARATION:  
A 28-DAY DIETARY STUDY IN RATS**

**PRODUCT IDENTIFICATION**

Soy Leghemoglobin Preparation

**PSL PROTOCOL NO.**

P703.01 IMP

**PERFORMING LABORATORY**

Product Safety Labs  
2394 US Highway 130  
Dayton, New Jersey 08810

**PSL STUDY NUMBER**

43166

**STUDY DIRECTOR**

Mithila Shitrit, BVSc & AH, MS

**SPONSOR**

Impossible Foods, Inc.  
525 Chesapeake Dr.  
Redwood City, CA 94063

**Product Safety Labs**

28-Day dietary Study in rats  
Protocol # P703.01 IMP  
PSL ID: 160720-5R  
Study No: 43166

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28-Day dietary Study in rats  
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## Product Safety Labs

28-Day dietary Study in rats  
Protocol # P703.01 IMP  
PSL ID: 160720-5R  
Study No: 43166

1. **TITLE OF STUDY: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS**
2. **OBJECTIVE**

The objective of this study is to evaluate the potential subchronic toxicity of Soy Leghemoglobin Preparation in male and female rats continuously exposed to the test substance in the diet for at least 28 days. A no-observed-adverse-effect-level (NOAEL) is sought for each sex.
3. **STUDY DIRECTOR**

Mithila Shitut  
Study Director  
Tel: 732-438-5100 x1558  
Email: [MithilaShitut@ProductSafetyLabs.com](mailto:MithilaShitut@ProductSafetyLabs.com)
4. **NAME AND ADDRESS OF THE TESTING FACILITY**

Product Safety Labs (PSL)  
2394 US Highway 130  
Dayton, NJ 08810  
Tel: 732 438 5100
5. **SPONSOR**

Impossible Foods, Inc.  
525 Chesapeake Dr.  
Redwood City, CA 94063
6. **SPONSOR REPRESENTATIVE**

Rachel Fraser  
Impossible Foods, Inc.  
525 Chesapeake Dr.  
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Email: [rachel.fraser@impossiblefoods.com](mailto:rachel.fraser@impossiblefoods.com)
7. **DATES**

Proposed In-Life Start Date: 9/28/16  
Proposed Experimental Termination Date: 10/28/16
8. **TEST SUBSTANCE**
  - 8.A **Source**

The test substance will be provided by the Sponsor.

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### 8.B Identification

The test substance will be identified using the following information provided by the Sponsor and Product Safety Labs (PSL) identification number.

Test Substance: Soy Leghemoglobin Preparation  
PSL ID: 160720-SR  
Lot #: PP-PGM2-16-088-301  
Physical Description: Red/brown powder  
Composition: Soy Leghemoglobin 48.82%  
Storage Conditions: Frozen  
Expiration Date: Not Applicable

Documentation of the methods of synthesis, fabrication, or derivation of the test substance is retained by the Sponsor.

### 8.C Analysis

The test substance, as received, is expected to be stable for the duration of the study. Stability of the test substance in the dietary matrix and that of the concentration of the test substance in the test diets will be determined as part of this study.

### 8.D Hazards

Appropriate routine safety precautions will be exercised in the handling of the test substance unless otherwise indicated by the Sponsor.

## 9. GENERAL TEST SYSTEM PARAMETERS

### 9.A Animal Requirements

- 9.A.1 Number of Animals: 80
- 9.A.2 Number of Groups: 4 (3 dietary levels per sex + 1 control group per sex)
- 9.A.3 Number of Animals per Group: 20 (10 male, 10 female)
- 9.A.4 Sex: Male and female; females will be nulliparous and non-pregnant.
- 9.A.5 Species/Strain: CRL Sprague-Dawley CD<sup>®</sup> IGS rats
- 9.A.6 Age/Weight: Seven to eight weeks at initiation; the weight variation will not exceed  $\pm 20\%$  of the mean weight for each sex.
- 9.A.7 Supplier: Charles River Laboratories, Inc. Rats will be shipped in filtered cartons by airfreight and/or truck.

### 9.B Test System Justification

The Sprague-Dawley<sup>®</sup> rat is the system of choice because, historically, it has been a preferred and commonly used species for dietary toxicity tests. The current state of scientific knowledge does not provide acceptable alternatives to the use of live animals to accomplish the objective of this study.

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### 9.C Husbandry

#### 9.C.1 Housing

The animals will be group housed in suspended stainless steel cages, which conform to the size recommendations in the latest *Guide for the Care and Use of Laboratory Animals*<sup>1</sup>. Litter paper placed beneath the cage will be changed at least three times/week. The animal room will have a 12-hour light/dark cycle and will be kept clean and vermin free. Environmental controls are set to maintain temperature and relative humidity ranges of  $21 \pm 2^\circ\text{C}$  and 30-70%, respectively. Observed ranges will be documented in the raw data.

#### 9.C.2 Acclimation

The animals will be conditioned to the housing facilities for at least five days prior to testing. Body weights and clinical observations will be recorded at least two times prior to study start.

#### 9.C.3 Feed

2016 Certified Envigo Teklad Global Rodent Diet<sup>®</sup> will be stored in a dedicated temperature and humidity monitored feed storage site and will be available *ad libitum* during acclimation. Test diets will be prepared as described in Section 11.B using 2016 certified Envigo Teklad Global Rodent Diet<sup>®</sup> and will be available *ad libitum* during the study.

#### 9.C.4 Water

Filtered tap water will be available *ad libitum* from individual bottles attached to the cages or from an automatic watering access system. Water analysis is conducted by Precision Analytical Services, Inc., Toms River, NJ and South Brunswick Municipal Water Supply, South Brunswick, NJ.

#### 9.C.5 Contaminants

There are no known contaminants reasonably expected to be found in the food or water that would interfere with the results of this study. Routine analysis consisting of each lot of feed used in this study will be received from Envigo Teklad, Madison, WI. Water analysis is conducted periodically and the records are kept on file at Product Safety Labs. The date(s) of the most recent analyses will be reported in the final report.

#### 9.C.6 Viral Screen

Serum samples from naive rats housed in the same room as test animals, as part of PSL's sentinel health monitoring program, will be evaluated for the absence of viruses near the end of the in-life portion of the study (PSL SOP #755).

<sup>1</sup> National Research Council. (2011). *Guide for the Care and Use of Laboratory Animals (8th ed.)*. Washington, DC: The National Academies Press.

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### 9.D Identification

#### 9.D.1 Cage

Each cage will be identified by a cage card indicating at least the study number, dose level, group assignment, individual animal identification and sex of the animals.

#### 9.D.2 Animal

Each animal will be given a sequential number in addition to being uniquely identified with a Monel<sup>®</sup> self-piercing stainless steel ear tag.

## 10. EXPERIMENTAL DESIGN

### 10.A Route of Administration

The test substance will be administered in the diet.

### 10.B Justification of Route of Administration

The dietary route of administration will be used because it is recommended in the referenced guidelines (Section 14.C.), and because human exposure may occur via this route.

### 10.C Control of Bias

Animals will be randomly assigned to test groups according to PSL SOP # 714.

### 10.D Dose Levels

Ten male and ten female test animals will be randomly assigned to each of the following test groups:

Group	No. Animals/ Group M/F	Dietary Dose Level/ Target Exposure of Active Ingredient (mg/kg/day)	Dietary Dose Level/ Target Exposure of Test Substance <sup>1</sup> (mg/kg/day)
1	10/10	0	0
2	10/10	250	512
3	10/10	500	1024
4	10/10	750	1536

<sup>1</sup>Based on 48.82% active ingredient (AI, Soy Leghemoglobin) of Soy Leghemoglobin Preparation lot # PP-PGM2-16-088-301

### 10.E Justification of Dose Level Selection

The Sponsor, in consultation with the Study Director, and based on a 14-day palatability/toxicity study (43167<sup>1</sup>) selected target dietary dose levels of 512, 1024 and 1536 mg/kg/day that correspond to target dose levels of 250, 500 and 750 mg/kg/day of the active ingredient, Soy leghemoglobin. To maintain target dietary dose levels throughout the study, concentrations in the test diets will be calculated based on the most recent group body weight and food consumption data. Alternatively, historical control values, relevant to the age and weight of the rats at

<sup>1</sup> Product Safety Labs (2016). Soy Leghemoglobin Preparation, Purified Soy Leghemoglobin Preparation and Bovine Erythrocytes: A 14-day dietary toxicity/palatability study in rats (In Draft).



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corresponding intervals will be used. Diets for males and females at each dietary dose level will be made separately each week. A NOAEL is expected to be achieved for this study.

### 11. GENERAL PROCEDURES

#### 11.A Selection of Animals

Eighty (80) healthy rats (forty males; forty females) will be used on test. Animals will be selected for this study on the basis of adequate body weight gain, absence of clinical signs of disease or injury, and a body weight within  $\pm 20\%$  of the mean within a sex. Selected rats will be distributed by randomization according to stratification by body weight so that there will be no statistically significant difference among group body weight means within a sex.

#### 11.B Diet Preparation and Sampling

##### 11.B.1 Diet Preparation (PSL SOP #605)

The test substance will be processed as needed to decrease particle size using a grinder and then added to 2016 Envigo Teklad Global Rodent Diet<sup>®</sup> and thoroughly mixed in a high-speed mixer. Control diet will be mixed under the same conditions as the diets prepared with the test substance. All diets will be kept frozen following preparation, unless presented to the test animals on the same day as diet preparation. All diets will be prepared approximately weekly.

##### 11.B.2 Diet Presentation

The control and test diets will be presented to their respective groups on Day 0 of the study. The diets will be replaced concurrently with food consumption measurements on Days 3, 7, 10, 14, 17, 21 and 24. Additional diet may be provided as needed throughout the study to insure *ad libitum* feeding. Animals will be exposed to the test diets for at least 28 days.

##### 11.B.3 Sampling (PSL SOP #607)

The neat test substance and selected prepared diets (at each concentration), will be sampled in duplicate.

##### 11.B.4 Stability of Test Substance

At the initial, middle, and final diet preparation, a sample of the test substance (neat) will be retained for stability. Analytical results of the initial and final stability samples will be used to establish the stability of the test substance under normal laboratory conditions for the duration of the study.

##### 11.B.5 Stability in Dietary Matrix

During the first week of the study, samples to verify the stability of the test and control substance in the dietary matrix will be prepared. Samples will be prepared in standard feed jars with followers and retaining rings and will be stored at ambient temperature in the animal room. Samples from each dietary concentration will be collected at the first presentation of the diet and after 4, 7, and 10 days and frozen until analyzed.

##### 11.B.6 Homogeneity

Samples to evaluate homogeneity of the test and control substance distribution will be collected from the initial diet preparation. Samples will be taken from approximately the top, middle and bottom of the diet mixer. Basal diet control samples will be collected

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from the middle of the mixer only. Chemical analysis will verify the diets as homogeneous and of accurate concentration throughout the study.

### 11.B.7 Concentration Verification

Samples will be collected from representative animal diets of the initial (as part of the homogeneity assessment), middle and final diet preparations during which time samples will be retained and stored frozen. Samples will be analyzed to verify the concentration of the test diets.

### 11.B.8 Sample Preservation

Upon sampling, diet preparations and neat test substance will be stored frozen. Samples will be considered stable from the point at which they are frozen.

### 11.B.9 Sample Analysis

A single duplicate of the frozen diet samples described above will be sent to Impossible Foods for analysis of diet preparation and neat test substance samples. A signed, analytical report will be provided to the Study Director. This report will include the methodology, pertinent measurements, study results, and tabulated results. Upon completion of the report, all raw data will be transferred to the Study Director to be incorporated into the main study report. Any remaining sample material will be retained at Product Safety Labs until issuance of the final report.

## 11.C Analytical Chemistry

### 11.C.1 Sample Storage

Upon receipt, all samples will be stored and maintained frozen (approximately -20°C) prior to analysis.

### 11.C.2 Method Validation

Prior to sample analysis, the suitability of the methods will be demonstrated. Method validation will include, but is not limited to determination of linearity, precision, and accuracy.

### 11.C.3 Reference Substance

Alliquots of the neat test substance will serve as the reference standard.

### 11.C.4 Chemical Analysis

Analytical test methodology will be validated by Impossible Foods personnel. Samples will be analyzed in replicate. A detailed description of the analytical test method(s) will be documented. Any remaining sample material will be retained until the issuance of the final report.

### 11.C.5 Data Reporting

Data will be captured on standard raw data sheets and as instrument output, as necessary, and summarized in tabular form.

### 11.C.6 Analytical Report and Records to be Maintained

A signed, analytical report will be provided to the Study Director. This report will include the methodology, pertinent measurements, study results, and tabulated results. Upon completion of the report, all raw data will be transferred to the Study Director. The analytical report will be incorporated into the main study report.

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### 11.D Ophthalmologic Evaluations

During the acclimation period, the eyes of all rats being considered for study will be examined by focal illumination, indirect ophthalmoscopy and, when indicated, slit-lamp microscopy. Mydriatic eye drops will be administered prior to ophthalmoscopy and the eyes will be examined in subdued light. Subdued light will be maintained in the animal room according to PSL SOP #737. These procedures will be repeated on all surviving test animals prior to test termination.

### 11.E Clinical Observations

All animals will be observed at least twice daily for viability. Cage-side observations of all animals will be performed daily during the study. All findings will be recorded.

On Day 0, prior to the first treatment with the test substance, and approximately weekly thereafter, a detailed observation will be conducted (PSL SOP #726) while handling the animal, generally on days that the animals are weighed and food consumption measurements are taken. Potential signs noted should include, but not be limited to: changes in skin, fur, eyes, and mucous membranes, occurrence of secretions and excretions and autonomic activity (e.g., lacrimation, piloerection, pupil size, unusual respiratory pattern). Likewise, changes in gait, posture and response to handling as well as the presence of clonic or tonic movements, stereotypes (e.g., excessive grooming, repetitive circling), or bizarre behavior (e.g., self-mutilation, walking backwards) should also be recorded. The date and clock time of all observations and/or mortality checks will be recorded.

The Study Director will be promptly notified of severe/remarkable clinical observations and will be advised when an animal is found in a moribund condition and may authorize euthanasia and necropsy as necessary to avoid the loss of quality data. All such authorizations will be recorded in the raw data.

### 11.F Body Weight and Body Weight Gain

Individual body weights will be recorded at least two times during acclimation. Test animals will be weighed on Day 0 (prior to study start) and approximately weekly thereafter (intervals of 7 days  $\pm$  1). Decedents need not be weighed. Body weight gain will be calculated for selected intervals and for the study overall.

### 11.G Food Consumption, Food Efficiency, and Dietary Intake of Soy Leghemoglobin Preparation

Individual food consumption will be measured and recorded on Days 3, 7, 10, 14, 17, 21, 24 and at the end of the study. Food efficiency and dietary intake of the test substance (mg/kg/day) will also be calculated and reported.

### 11.H Clinical Pathology

Clinical pathology will be performed on all surviving animals for blood chemistry and hematology of the terminal sacrifice animals once toward the end of the dosing phase of the study. The animals will be fasted overnight prior to blood collection. Blood samples for hematology (except coagulation samples) and clinical chemistry will be collected via sublingual bleeding under isoflurane anesthesia during approximately Week 4 of the test period. Approximately 500  $\mu$ L of blood will be collected in a pre-calibrated tube containing K<sub>2</sub>EDTA for hematology assessments. The whole blood samples will be stored under refrigeration and shipped on cold packs. Approximately 1000  $\mu$ L of blood will be collected into a tube containing

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no preservative for clinical chemistry assessments. These samples will be centrifuged in a refrigerated centrifuge and the serum will be transferred to a labeled tube. Serum samples will be stored in a -80°C freezer and shipped frozen on dry ice. All samples will be shipped to DuPont Haskell Global Centers for Health and Environmental Sciences.

The day before collection of samples for the clinical pathology evaluation, the animals will be placed in metabolism cages. Animals will be fasted after 3 pm (at least 15 hours prior to) and urine will be collected from each animal. Urine samples will be stored under refrigeration and shipped on cold packs or wet ice to DuPont Haskell Global Centers for Health and Environmental Sciences.

Blood samples used to determine the prothrombin time and activated partial thromboplastin time (coagulation) will be collected via the inferior vena cava under isoflurane anesthesia at terminal sacrifice. Approximately 1.8 mL of blood will be collected in a pre-calibrated tube containing 3.2% sodium citrate. These samples will be centrifuged in a refrigerated centrifuge and the plasma will be transferred to labeled tubes. Plasma samples will be stored in a -80°C freezer and shipped frozen in dry ice to DuPont Haskell Global Centers for Health and Environmental Sciences. In addition, a second blood sample will be retained during the exsanguination procedure for future possible evaluation if treatment related effects are identified. Details of this evaluation will be added by amendment.

All blood samples will be evaluated for quality by visual examination.

### 11.H.1 Hematology: Will include:

erythrocyte count (RBC)	hemoglobin concentration (HGB)
hematocrit (HCT)	mean corpuscular volume (MCV)
mean corpuscular hemoglobin (MCH)	red cell distribution width (RDW)
absolute reticulocyte count (ARET)	platelet count (PLT)
total white blood cell (WBC) and differential leukocyte count	
Mean corpuscular hemoglobin concentration (MCHC) will be calculated.	

In addition, separate, blood smears, stained with New Methylene Blue or Wright-Giemsa stain, will be prepared from each animal undergoing hematological evaluation and will be examined, if required, to substantiate or clarify the results of hematology findings.

### 11.H.2 Coagulation: Will include:

prothrombin time (PT)  
activated partial thromboplastin time (APTT)

### 11.H.3 Clinical chemistry: Will include:

serum aspartate amino transferase (AST)	serum alanine aminotransferase (ALT)
sorbital dehydrogenase (SDH)	alkaline phosphatase (ALKP)
total bilirubin (BILI)	urea nitrogen (BUN)
blood creatinine (CREA)	total cholesterol (CHOL)
triglycerides (TRIG)	fasting glucose (GLUC)
total serum protein (TP)	albumin (ALB)
globulin (GLOB)	calcium (CALC)
inorganic phosphorus (IPHS)	sodium (NA)
potassium (K)	chloride (CL)

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### 11.H.4 Urinalysis: Will include:

quality (QUAL)	pH	ketone (KET)
color (COL)	glucose (UGLC)	bilirubin (UBIL)
clarity (CLAR)	specific gravity (SG)	blood (BLD)
volume (UVOL)	protein (UMTP)	urobilinogen (URO)
microscopic urine sediment examination		

Any remaining serum samples will be maintained frozen at approximately -80°C and discarded upon approval of the Sponsor at finalization.

## 11.I Terminal Sacrifice and Histopathology

### 11.I.1 Scheduled Sacrifice

At terminal sacrifice, all survivors will be euthanized by exsanguination from the abdominal aorta under isoflurane anesthesia. All animals in the study (including decedents) will be subjected to a gross necropsy, which will include examination of the external surface of the body, all orifices, musculoskeletal system, and the cranial, thoracic, abdominal, and pelvic cavities, with their associated organs and tissues. All gross lesions will be recorded. The following tissues (of all animals sacrificed by design) will be weighed wet as soon as possible after dissection to avoid drying:

adrenals (combined)	kidneys (combined)	spleen
brain	liver	thymus
epididymides (combined)	ovaries with oviducts (combined)	uterus
heart	testes (combined)	

The following organs and tissues from all animals will be preserved in 10% neutral buffered formalin for possible future histopathological examination:

accessory genital organs (prostate and seminal vesicles)	ileum with Peyer's patches	rectum
adrenals	jejunum	salivary glands (sublingual submandibular, and parotid)
all gross lesions	kidneys	skeletal muscle
aorta	larynx	skin
bone (femur)	liver	spinal cord - 3 levels: cervical, mid- thoracic, and lumbar
bone marrow (from femur & sternum)	lungs	spleen
brain - 3 sections including medulla/pons, cerebellar, and cerebral cortex	lymph node mandibular	sternum
cecum	lymph node mesenteric	stomach
cervix	mammary gland	thymus
colon	nasal turbinates	thyroid
duodenum	nose	trachea
esophagus	ovaries	urinary bladder
Harderian gland	oviducts	uterus
heart	pancreas	vagina
	parathyroid	
	peripheral nerve (sciatic)	
	pharynx	
	pituitary gland	

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The following organs and tissues from all animals will be preserved in modified Davidson's fixative and then stored in ethanol for possible future histopathological examination:

eyes	optic nerve
epididymides	testes

Additional tissues will be preserved if indicated by signs of toxicity or target organ involvement.

### 11.1.2 Unscheduled Sacrifice

Any rat that dies or is sacrificed because of a moribund condition will be examined for the cause of death or moribund condition on the day the observation is made. Rats will be evaluated for gross lesions. Organs and tissues will be excised, weighed (except for animals found dead), and preserved as described for those animals sacrificed by design.

### 11.1.3 Histopathology

Histological examination will be performed on the preserved organs and tissues of the animals from both the control and high dose groups (Groups 1 and 4, respectively) as well as from any animal that dies during the course of the study. In addition, gross lesions of potential toxicological significance noted in any test groups at the time of terminal sacrifice will also be examined. These examinations may be extended to other tissues and organs from the low and intermediate groups at the request of Pathologist in consultation with the Study Director and Sponsor to further investigate changes observed in the high dose group. The fixed tissues will be trimmed, processed, embedded in paraffin, sectioned with a microtome, placed on glass microscope slides, stained with hematoxylin and eosin (HE) and examined by light microscopy. Additional special stains can be added based on HE evaluation at the discretion of the study pathologist in consultation with the study director and sponsor. Slide preparation and histological assessment, by a board-certified veterinary pathologist, will be performed at Hist-Scientific Research Laboratories (HSRL).

## 12. STATISTICAL ANALYSIS

Product Safety Labs will perform statistical analysis of all data collected during the in-life phase of the study as well as organ weight data, if applicable. The use of the word "significant" or "significantly" indicates a statistically significant difference between the control and the experimental groups. Significance will be judged at a probability value of  $p < 0.05$ . Male and female rats will be evaluated separately.

### 12.A Statistical Methods (In-Life and Organ Weight Data):

Mean and standard deviations will be calculated for all quantitative data. If warranted by sufficient group sizes, data within groups will be evaluated for homogeneity of variance<sup>1</sup> and normality. Where homogeneous variance and normal distribution is observed, treatment and control groups will be compared using a one-way analysis of variance (ANOVA). When one-way analysis of variance is significant, a comparison of treated groups to control for multiple comparisons will be performed (e.g. Dunnett's test)<sup>2,3</sup>. Where variance is considered significantly

<sup>1</sup> Bartlett, M.S. (1937). Properties of sufficiency and statistical tests. *Proceedings of the Royal Statistical Society Series A*, 160, 268-282.

<sup>2</sup> Dunnett, C.W. (1964). New tables for multiple comparisons with a control. *Biometrics*, 20(3), 482-491.

<sup>3</sup> Dunnett, C.W. (1980). Pairwise multiple comparisons in the unequal variance case. *J. Amer. Statist. Assoc.*, 75, 796-800.

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different, groups will be compared using a non-parametric method (e.g. Kruskal-Wallis non-parametric analysis of variance)<sup>1</sup>. When non-parametric analysis of variance is significant, a comparison of treated groups to control will be performed (e.g. Dunn's test)<sup>2</sup>.

If warranted by sufficient group sizes, the incidence of clinical observations may be evaluated through sequential application of a trend test<sup>3</sup>. Other procedures will be used if appropriate, and will be described in the final report.

Statistical analysis will be conducted using one or more of the following software applications: Provantis<sup>®</sup> version 9, Tables and Statistics, Instem LSS, Staffordshire UK; INSTAT or Prism Biostatistics, Graph Pad Software, San Diego, CA; Statview, version 5, SAS Institute Inc.; and SigmaStat, version 2. Other statistical methods will be used if appropriate, at the time of analysis, and described in the final report.

### 12.B Statistical Methods (Clinical Pathology)

Significance will be judged at a probability value of  $p < 0.05$ . Males and females will be analyzed separately (Provantis<sup>™</sup> version 8, Tables and Statistics, Instem LSS, Staffordshire UK).

Parameter	Preliminary Test	Method of Statistical Analysis	
		If preliminary test is not significant	If preliminary test is significant
Clinical Pathology <sup>4</sup>	Levene's <sup>4</sup> test for homogeneity and Shapiro-Wilk <sup>5</sup> test for normality	One-way analysis of variance followed with Dunnett's test	Transforms of the data to achieve normality and variance homogeneity will be used. The order of transforms attempted will be log, square root, and rank-order. If the log and square root transforms fail, the rank-order will be used.

<sup>4</sup> When an individual observation is recorded as being less than a certain value, calculations are performed on half the recorded value. For example, if bilirubin is reported as <0.1, 0.05 is used for any calculations performed with that bilirubin data. When an individual observation is recorded as being greater than a certain value, calculations are performed on the recorded value. For example, if specific gravity was reported as >1.100, 1.100 is used for any calculation performed with that specific gravity data.

Other statistical methods will be used if appropriate, at the time of analysis. The statistical methods used will be described in the final report.

### 13. FINAL REPORT

A signed study report will be provided to the Sponsor. This report will include, but not be limited to, the following information:

- individual animal data (and averages where appropriate) for actual concentration of test substance received; time of observation of each abnormal sign and its subsequent course;
- body weights, food consumption and food efficiency values;
- ophthalmological assessments;

<sup>1</sup> Kruskal, W.H., & Wallis, W.A. (1952). Use of ranks in one-criterion variance analysis. *J. Amer. Statist. Assoc.*, 47, 583-621.

<sup>2</sup> Dunn, O.J. (1984). Multiple contrasts using rank sums. *Technometrics*, 6, 241-252.

<sup>3</sup> Agresti, A. (2013). *Categorical Data Analysis* (3<sup>rd</sup> Edition). John Wiley & Sons, Inc. Hoboken, NJ.

<sup>4</sup> Levene, H. (1960). Robust tests for equality of variances. In: I. Olkin et al (Eds), *Contributions to probability and statistics* (pp. 278-292). Palo Alto, CA: Stanford University Press.

<sup>5</sup> Shapiro, S.S. & Wilk, M.B. (1965). An analysis of variance test for normality (complete samples). *Biometrika*, 52(3-4), 591-611.

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- hematology, clinical chemistry, coagulation, and urinalysis results;
- organ weights, organ to body weight and organ to brain weight ratios;
- necropsy and pathology findings;
- test substance and dose preparation analysis;
- a compliance statement signed by the Study Director that states that the report accurately reflects the raw data obtained during the performance of the study and that all applicable GLP regulations were followed in the conduct of the study;
- a Quality Assurance statement summarizing QA activities performed for the study.

### 14. STUDY CONDUCT

#### 14.A Laboratory

In-life portion	Product Safety Labs 2394 US Highway 130 Dayton, NJ 08810
Ophthalmology evaluation	Kristina R. Vygantas, DVM, DACVO 319 Perrineville Rd. Robbinsville, NJ 08691
Clinical chemistry, hematology, coagulation, and urinalysis	Dupont Haskell Global Centers for Health and Environmental Sciences P.O. Box 30 Elkton Road Newark, DE 19714 P.I.: Denise Hoban, BA, MLT, ASCP
Clinical pathology evaluation	Product Safety Labs 2394 US Highway 130 Dayton, NJ 08810 P.I.: Odete Mendes, DVM, PhD, DACVP, DABT
Test substance and dietary analysis	Impossible Foods, Inc 525 Chesapeake Dr. Redwood City, CA 94063 Prospective P.I.: Rachel Fraser, PhD
Histological slide preparation	Histo-Scientific Research Laboratories (HSRL) 5930 Main Street Mount Jackson, VA 22842 P.I. (histology): Craig Zook
Histological slide evaluation	Histo-Scientific Research Laboratories (HSRL) 5930 Main Street Mount Jackson, VA 22842 Prospective P.I.(s) (pathology): David Gartick, DVM, DACVP Laura E. Elcock, DVM, PhD, DACVP Elizabeth H. Hutto, DVM, PhD, DACVP Daphne Vasconcelos, DVM, PhD, DACVP, DABT Allen Singer, DVM, DACVP, DABT



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### 14.B GLP Compliance

This study will be conducted in compliance with the following regulations:

- U.S. FDA GLP: 21 CFR Part 58, 1987

Which is compatible with:

- OECD Principles of Good Laboratory Practice (as revised in 1997) published in ENV/MC/CHEM (98)17, OECD, Paris, 1998.

Clinical pathology evaluation will be conducted in compliance with U.S. FDA GLP: 21 CFR Part 58, 1987 which is compatible with OECD Good Laboratory Practices.

Analytical chemistry will be performed in conformance with GLP principles in a non-GLP facility.

### 14.C Test Procedure Guidelines

This study design is based on the following guidelines:

- OECD Guidelines for Testing of Chemicals and Food Ingredients, Section 4 (Part 407): Health Effects, Repeated Dose 28-Day Oral Toxicity Study in Rodents (2008).
- US FDA Toxicological Principles for the Safety Assessment of Food Ingredients, Redbook 2000, IV.C. 4. a. *Subchronic Toxicity Studies with Rodents* (2007).

## 15. QUALITY ASSURANCE

The Quality Assurance Unit (QAU) of PSL has reviewed this protocol for GLP compliance and will conduct in-process inspections of selected procedures during the study. The final report will be audited for agreement with the raw data records and for compliance with the protocol and PSL SOPs.

In addition, PSL QAU will function as lead QA for this study and will monitor QA activities at DuPont Haskell Global Centers for Health and Environmental Sciences and HSRL. For portions of the study conducted by a subcontractor, the QAU for that facility will conduct necessary critical phase inspections and audit respective results and reports for the study phase according to the SOPs of that facility.

The QA Units from DuPont Haskell Global Centers for Health and Environmental Sciences and HSRL will send all GLP audit reports to the Study Director, Study Director's management, and PSL QAU as soon as they are issued.

## 16. RECORDS TO BE MAINTAINED

The original signed report will be sent to the Sponsor. A copy of the signed report, together with the protocol and all raw data generated at Product Safety Labs, will be maintained in the Product Safety Labs Archives. PSL will maintain these records for a period of at least five years. After this time, the Sponsor of the study will be offered the opportunity to take possession of the records or will be charged an archiving fee for continued archiving by PSL.

The following records will be maintained:

- A. Information on test substance will include but not be limited to the following:

Storage	Dietary analysis
Usage	Test substance analysis
Disposition	

## Product Safety Labs

28-Day dietary Study in rats  
Protocol # P703.01 IMP  
PSL ID: 160720-5R  
Study No: 43166

**B.** Information on animals will include, but not be limited to the following:

Receipt, date of birth	Clinical observations
Initial health assessment	Histopathology data
Dosing	Individual necropsy records
Body weights	Organ weights
Food consumption	Ophthalmologic evaluations
Hematology, clinical chemistry, coagulation, urinalysis data	

**C.** All other records that would demonstrate adherence to the protocol.

Raw data related to hematology and clinical chemistry evaluations will be maintained by Product Safety Labs and/or DuPont Haskell Global Centers for Health and Environmental Sciences, Newark, DE. Prepared slides and pathology data will be maintained by Product Safety Labs and/or by HSRL, 5930 Main Street, Mount Jackson, VA, 22842. Test substance and dietary analysis data will be maintained by Impossible Foods, Inc. 525 Chesapeake Dr. Redwood City, CA 94063.

**17. PROTOCOL AMENDMENTS AND DEVIATIONS**

All amendments to this protocol and the reasons therefore shall be documented, signed by the Study Director, dated and maintained with the raw data and protocol. Any deviations from this protocol will be recorded in the raw data and documented in the final report.

**18. DISPOSITION OF TEST SUBSTANCE**

A reserve sample of the test substance and records of sample disposition will be maintained at Product Safety Labs. All remaining test substance will be retained for at least one year from receipt, unless otherwise specified by the Sponsor. All remaining test substance will be returned to the Sponsor unless otherwise directed.

## Product Safety Labs

28-Day dietary Study in rats  
Protocol # P703.01 IMP  
PSL ID: 160720-5R  
Study No: 43166

### 19. PROTOCOL APPROVAL

(b) (6)  
Signature: \_\_\_\_\_  
Rachel Fraser, PhD  
Sponsor Representative  
Impossible Foods, Inc.  
Date: 9/16/16

(b) (6)  
Signature: \_\_\_\_\_  
Mithila Shitka, BVSc & AH, MS  
Study Director  
Product Safety Labs  
Date: 9/21/16

(b) (6)  
Signature: \_\_\_\_\_  
Odete Mendes, DVM, PhD, DACVP, DABT  
Director of Toxicology and Pathology  
Product Safety Labs  
Date: 16 Sep 16

### 20. PROTOCOL REVIEW

(b) (6)  
Signature: \_\_\_\_\_  
Rhonda S. Krick, BS  
Quality Assurance Director  
Product Safety Labs  
Date: Sep 16, 2016

New Date: 09/16/16

## Product Safety Labs

### PROTOCOL AMENDMENT

#### SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

PROTOCOL NO.: P703.01 IMP

AMENDMENT NO.: 1

STUDY NO.: 43166

PSL Sample IDs: 160720-5R

**PROTOCOL SECTION (change from): 11.F Body Weight and Body Weight Gain**

Individual body weights will be recorded at least two times during acclimation. Test animals will be weighed on Day 0 (prior to study start) and approximately weekly thereafter (intervals of 7 days  $\pm$  1). Decedents need not be weighed. Body weight gain will be calculated for selected intervals and for the study overall.

**PROTOCOL SECTION (change to): 11.F Body Weight and Body Weight Gain**

Individual body weights will be recorded at least two times during acclimation. Test animals will be weighed on Day 0 (prior to study start) and approximately weekly thereafter (intervals of 7 days  $\pm$  1). **The animals will also be weighed prior to sacrifice in order to calculate organ to body weight ratios.** Decedents need not be weighed. Body weight gain will be calculated for selected intervals and for the study overall.

**REASON:** Terminal body weight was not included in the protocol.

**EFFECTIVE DATE:** September 28, 2016

(b) (6)

Mithila Shitka, BVSc & AH, MS  
Study Director  
Product Safety Labs

9/28/16  
Date

## Product Safety Labs

### PROTOCOL AMENDMENT

#### SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

PROTOCOL NO.: P703.01 IMP

AMENDMENT NO.: 2

STUDY NO.: 43166

PSL NO.: 160720-5R

PROTOCOL SECTION: 14.A. Laboratory

**Change from:**

Histological slide evaluation	Histo-Scientific Research Laboratories (HSRL) 5930 Main Street Mount Jackson, VA 22842 Prospective P.I.(s) (pathology): David Garlick, DVM, DACVP Laura E. Elcock, DVM, PhD, DACVP Elizabeth H. Hutto, DVM, PhD, DACVP Daphne Vasconcelos, DVM, PhD, DACVP, DABT Allen Singer, DVM, DACVP, DABT
-------------------------------	--

**Change to:**

Histological slide evaluation <b>(Change in bold)</b>	Histo-Scientific Research Laboratories (HSRL) 5930 Main Street Mount Jackson, VA 22842 Prospective P.I.(s) (pathology): David Garlick, DVM, DACVP Laura E. Elcock, DVM, PhD, DACVP Elizabeth H. Hutto, DVM, PhD, DACVP Daphne Vasconcelos, DVM, PhD, DACVP, DABT Allen Singer, DVM, DACVP, DABT <b>Daniel G. Branstetter, DVM, PhD, DACVP</b>
--	---

EFFECTIVE DATE: November 1, 2016

(b) (6)

Mithila Shitut, BVSc & AH, MS  
Study Director  
Product Safety Labs

12/23/16

Date

## Product Safety Labs

### PROTOCOL AMENDMENT

SOY LEGHEMOGLOBIN PREPARATION:  
A 28-DAY DIETARY STUDY IN RATS

PROTOCOL NO.: P703.01 IMP

AMENDMENT NO.: 3

STUDY NO.: 43166

PSL NO.: 160720-5R

PROTOCOL SECTION: 11.I

Add to section 11.I.

11.1.4 Histopathology Peer Review

A histopathology peer review of female reproductive organs will be performed for all female rats. The peer review pathologist will be Karen Regan, DVM, DABT, DACVP from Regan Path/Tox Services, Inc, 1457 Township Road 853, Ashland, OH 44805. A peer review statement will be inserted in the final study report.

EFFECTIVE DATE: June 1, 2017

(b) (6)

\_\_\_\_\_  
Mithila Shitut, BVSc & AH, MS  
Study Director  
Product Safety Labs

June 1, 2017

\_\_\_\_\_  
Date

## **APPENDIX B: FEED, WATER, AND SEROLOGY ANALYSES**

### **PRODUCT IDENTIFICATION**

Soy Leghemoglobin Preparation

APPENDIX B (cont.): FEED

2016C



+++  
ENVIGO

Teklad Certified Global 16% Protein Rodent Diet

Lot Number 2016C-080216MA  
Date of Manufacture 08/02/16  
Report Date 08/16/16

Analysis	Result (%)
Protein	16.40
Fat	3.83
Fiber	2.96
Moisture	10.33
Ash	4.74
Calcium	0.94
Phosphorus	0.63

**Laboratory Diet Certification Report**

The following data is a consolidation of results obtained from one or more independent testing laboratories. The actual laboratory results are available upon request.

(b) (6) I have reviewed this document 2016.08.16 12:37:20 -05'00'

Analysis	Result	Units	Established Maximum Concentration
<b>Heavy Metals</b>			
Arsenic	0.13	ppm	1.00
Cadmium	< 0.10	ppm	0.50
Lead	< 0.20	ppm	1.50
Mercury	< 0.05	ppm	0.20
Selenium	0.22	ppm	0.50
<b>Mycotoxins</b>			
Aflatoxin B1, B2, G1, G2	< 5.00	ppb	5.00
<b>Organophosphates</b>			
Aldrin	< 0.01	ppm	0.03
Lindane	< 0.01	ppm	0.05
Chlordane	< 0.01	ppm	0.05
DDT & related substances	< 0.03	ppm	0.15
Dieldrin	< 0.02	ppm	0.03
Endrin	< 0.02	ppm	0.03
Heptachlor	< 0.01	ppm	0.03
Heptachlor Epoxide	< 0.01	ppm	0.03
Toxaphene	< 0.10	ppm	0.15
PCBs	< 0.10	ppm	0.15
α-BHC	< 0.01	ppm	0.05
β-BHC	< 0.01	ppm	0.05
δ-BHC	< 0.01	ppm	0.05
Hexachlorobenzene	< 0.01	ppm	0.03
Mirex	< 0.01	ppm	0.02
Methoxychlor	< 0.05	ppm	0.50
<b>Organophosphates</b>			
Thimet	< 0.16	ppm	0.50
Diazinon	< 0.14	ppm	0.50
Disulfoton	< 0.15	ppm	0.50
Methyl Parathion	< 0.14	ppm	0.50
Malathion	< 0.14	ppm	0.50
Parathion	< 0.12	ppm	0.50
Thiodan	< 0.02	ppm	0.50
Ethion	< 0.14	ppm	0.50
Trithion	< 0.15	ppm	0.50

Teklad Global Diets is a trademark of Envigo, © Envigo 2016

Envigo Teklad Diets + Madison WI + + tekladinfo@envigo.com (800) 483-5523



## **APPENDIX B (cont.): WATER**

In June 2015, water was analyzed for contaminants.

LABORATORY:       PRECISION ANALYTICAL SERVICES, INC.  
                          2161 Whitesville Road  
                          Toms River, NJ 08755

Results of water analysis for possible contaminants were acceptable within regulatory standards.



Specialties in Drinking Water Testing Technologies ■ Analytical ■ Industrial ■ Municipal  
1141 BRIDGEVILLE ROAD ■ NORTH BRIDGE, NJ 08955 ■ PHONE 732-914-1515 ■ FAX 732-914-1518

**CERTIFICATE OF ANALYSIS**

Customer: Product Safety Labs  
2354 Route 130  
Dayton, NJ 08810

Project ID: 2nd Quarter  
PAS Project ID P16-3141

Matrix: Drinking Water  
Report Date: 6/28/2016

PAS Sample ID	Client ID	Analyte	Results	Units	PQL	MCL	MCL	Method	Date Sampled	Date Analyzed
P16-3141-01	Room #7	Copper	ND	mg/L	0.05	0.0185	1.30	SM 3111 B	6/21/16 11:20	6/27/16 16:33
P16-3141-01	Room #7	Zinc	ND	mg/L	0.025	0.0092	5.00	SM 3111 B	6/21/16 11:20	6/28/16 13:34
P16-3141-01	Room #7	Lead	ND	mg/L	0.002	0.000462	0.005	SM 3113 B	6/21/16 11:20	6/23/16 18:15
P16-3141-01	Room #7	E. Coli / Coliform	Absent	Pres/Abs	1 Col/100ml	1 Col/100ml	0 Col/100ml	SM 9223 B	6/21/16 11:20	6/21/16 16:55
P16-3141-01	Room #7	Total Coliform / Coliform	Absent	Pres/Abs	1 Col/100ml	1 Col/100ml	0 Col/100ml	SM 9223 B	6/21/16 11:20	6/21/16 16:55
P16-3141-02	Room #10	Copper	ND	mg/L	0.05	0.0185	1.30	SM 3111 B	6/21/16 11:25	6/27/16 16:35
P16-3141-02	Room #10	Zinc	ND	mg/L	0.025	0.0092	5.00	SM 3111 B	6/21/16 11:25	6/28/16 13:36
P16-3141-02	Room #10	Lead	ND	mg/L	0.002	0.000462	0.005	SM 3113 B	6/21/16 11:25	6/23/16 15:19
P16-3141-02	Room #10	E. Coli / Coliform	Absent	Pres/Abs	1 Col/100ml	1 Col/100ml	0 Col/100ml	SM 9223 B	6/21/16 11:25	6/21/16 16:55
P16-3141-02	Room #10	Total Coliform / Coliform	Absent	Pres/Abs	1 Col/100ml	1 Col/100ml	0 Col/100ml	SM 9223 B	6/21/16 11:25	6/21/16 16:55
P16-3141-03	Room #29, Pressure Station	Copper	ND	mg/L	0.05	0.0185	1.30	SM 3111 B	6/21/16 11:35	6/27/16 16:38
P16-3141-03	Room #29, Pressure Station	Zinc	ND	mg/L	0.025	0.0092	5.00	SM 3111 B	6/21/16 11:35	6/28/16 13:39
P16-3141-03	Room #29, Pressure Station	Lead	ND	mg/L	0.002	0.000462	0.005	SM 3113 B	6/21/16 11:35	6/23/16 15:24
P16-3141-03	Room #29, Pressure Station	E. Coli / Coliform	Absent	Pres/Abs	1 Col/100ml	1 Col/100ml	0 Col/100ml	SM 9223 B	6/21/16 11:35	6/21/16 16:55
P16-3141-03	Room #29, Pressure Station	Total Coliform / Coliform	Absent	Pres/Abs	1 Col/100ml	1 Col/100ml	0 Col/100ml	SM 9223 B	6/21/16 11:35	6/21/16 16:55
P16-3141-04	Slipper Bottle	Total Coliform	ND	Col/100ml	1 Col/100ml	1 Col/100ml	0 Col/100ml	SM 9222 B	6/21/16 11:40	6/27/16 11:20
P16-3141-05	Slipper Tap	Total Coliform	MC Interference ***	Col/100ml	1 Col/100ml	1 Col/100ml	0 Col/100ml	SM 9222 B	6/21/16 11:40	6/22/16 11:20

Except for the parameters tested, PAS makes no representation as to the fitness or quality of the water sample taken.  
 \*\*\* Non Coliform Bacteria growth was found to be Confirmed and may interfere with the growth of Total Coliform Bacteria. The result is bracketed and retesting is required.  
 MC = Non-Coliform Bacteria  
 MCL = Maximum Contaminant Level  
 PQL = Practical Quantitation Limit  
 ND = Not Detected  
 Pres/Abs = Present/Absent  
 Col/100ml = Colony Forming Units per 100 milliliters  
 \* = Estimated result  
 \*\* = Estimated Arsenic Level

All samples are analyzed in accordance with New Jersey Department of Environmental Protection's protocols.

Mark D. Fehelton, Lab Director

① SCP 508 Dev. testing not repeated on slipper tap (M 7/6/16)  
 R. cm 13 faucet not analyzed due to room being out of service (b) 7/7/16  
 Animals are no longer given water from unfiltered source (downstream)  
 Missing sampling at room 13 has no impact.  
 Slipper bottle tested OK, no need to test slipper tap (tube)  
 (b) 7/7/16

(b) (6)  
 OK  
 07/07/16  
 MZ  
 07/10/16

## **APPENDIX B (cont.): SEROLOGY**

In October 2016, serology from sentinel animals residing in Room #15, which also housed the study animals, was obtained from collected blood serum for a battery of common viral and microbiologic pathogens.

The sentinel animals along with the test animals were in Room #34 from September 28, 2016, through October 28, 2016, for the duration of the study. Blood samples were collected on October 28, 2016.

LABORATORY:        IDEXX BioResearch  
                          4011 Discovery Drive  
                          Columbia, MO 65201

Results of the serology analyses for sentinel animals corresponding with this study are reported as samples 257M 10.28.16, 268M 10.28.16, and 316F 10.28.16. All samples were negative for microbial antibodies.



**FINAL REPORT OF LABORATORY EXAMINATION**

4011 Discovery Drive, Columbia, MO 65201

1-800-868-0825 1-573-499-5700

idexxbioresearch@idexx.com www.idexxbioresearch.com

**IDEXX BioResearch Case # 30789-2016**

**Received: 11/15/2016**

**Completed: 11/16/2016**

**Submitted By**

Mithila Shitut  
Product Safety Labs  
2394 US Highway 130  
Dayton, NJ 08810

Phone: 732-438-5100 ext. 1558  
Email: MithilaShitut@productsafetylabs.com

**Specimen Description**

Species: rat  
Description: Opti-Spot strip(s)  
Number of Specimens/Animals: 3

**Purchase Order #: P1602593UDC1**

Client ID	Investigator	Room #	Strain/Breed	Sex	Age	Study Number
257M 10.28.16	Mithila Shitut	15	CD/CRL	M	3m	43166
268M 10.28.16	Mithila Shitut	15	CD/CRL	M	3m	43166
316F 10.28.16	Mithila Shitut	15	CD/CRL	F	3m	43166

**Services/Tests Performed: Primary Serology Profile**

**Serologic evaluation for antibodies to: H1, KRV, RCV/SDAV, RMV, RPV, RTV**

**Summary: All test results were negative.**

If you have questions, please call our toll free number at 1-800-868-0825 or e-mail us at idexxbioresearch@idexx.com.

**SEROLOGY SUMMARY**

	25/M 10 28 16	26/M 10 28 16	31/F 10 28 16
RPV	-	-	-
RMV	-	-	-
KRV	-	-	-
H1	-	-	-
RCV/SDAV	-	-	-
RTV	-	-	-
Rat IgG	N	N	N

Legend: + = positive - = negative blank = test not performed EQ = equivocal HE = hemolysis precluded testing I = insufficient W = weak positive WB = Western Blot confirmatory analysis pending NS = non-specific reactivity N = normal IgG L = less than normal IgG



FINAL REPORT OF LABORATORY EXAMINATION

4011 Discovery Drive, Columbia, MO 65201

1-800-889-0825 1-573-499-5700

idexxbioresearch@idexx.com www.idexxbioresearch.com

IDEXX BioResearch Case # 30789-2016

Received: 11/15/2016  
Completed: 11/16/2016

SEROLOGY DETAILS

	Baseline	257M 10 28 16	308M 10 28 16	316F 10 28 16
<b>RPV</b>				
RPV purified virus	MFI > 2.000	-	-	-
NS1 <sup>1</sup>	MFI > 3.750	-	-	-
<b>RMV</b>				
RMV VP2 recombinant	MFI > 2.000	-	-	-
NS1 <sup>1</sup>	MFI > 3.750	-	-	-
<b>KRV</b>				
KRV purified virus	MFI > 2.500	-	-	-
NS1 <sup>1</sup>	MFI > 3.750	-	-	-
<b>H1</b>				
H1 purified virus	MFI > 1.750	-	-	-
NS1 <sup>1</sup>	MFI > 3.750	-	-	-
<b>RCV/SDAV</b>				
RCV/SDAV purified virus	MFI > 3.750	-	-	-
RCV/SDAV Spike	MFI > 3.750	-	-	-
<b>RTV</b>				
RTV purified virus	MFI > 2.000	-	-	-
TMEV purified virus	MFI > 2.000	-	-	-

NS1<sup>1</sup>: NS1 protein is highly conserved among rodent parvoviruses and thus serves as a generic assay for parvovirus seroconversion.

Legend: + = positive - = negative blank = test not performed EQ = equivocal HE = hemolysis precluded testing I = insufficient W = weak positive WB = Western Blot confirmatory analysis pending NS = non-specific reactivity N = normal IgG L = less than normal IgG

Positive MFI results are reported as "\*" followed by a number from 1 to 33 in thousands rounded off to the nearest thousand.

If you have questions, please call our toll free number at 1-800-889-0826 or e-mail us at idexxbioresearch@idexx.com

## **APPENDIX C: CERTIFICATES OF ANALYSIS**

### **PRODUCT IDENTIFICATION**

Soy Leghemoglobin Preparation

## Product Safety Labs

# CERTIFICATE OF ANALYSIS

**Product:** Soy Leghemoglobin Preparation

**Lot #:** PP-PGM2-16-088-301

**PSL Reference No.:** 160720-5R

**Date of Analysis:** August 16, 2016

**Result:**

**Soy Leghemoglobin – 48.82%**

Approval: (b) (6) \_\_\_\_\_ 9/17/16  
Date  
David Shuang  
Analytical Services  
Product Safety Labs

QA Release: (b) (6) \_\_\_\_\_ Sep 14, 2016  
Date  
Rhonda Krick, B.S.  
Quality Assurance  
Product Safety Labs

*This material was analyzed in compliance with Good Laboratory Practice (40 CFR 160) standards.  
Data are reported in PSL GLP Study No. 43682*



## **APPENDIX D: CHEMICAL ANALYSIS**

### **PRODUCT IDENTIFICATION**

Soy Leghemoglobin Preparation

# IMPOSSIBLE™

**Project Title:**

Analysis of Samples from Study:  
Soy Leghemoglobin Preparation: A 28-DAY DIETARY STUDY IN RATS

**Sponsor**

Impossible Foods, Inc.  
525 Chesapeake Dr.  
Redwood City, CA 94063

**ANALYTICAL REPORT**

**Test Substance:**

160720-SR

**Author:**

Pavel A. Aronov, PhD

**Analytical Report Completion Date:**

December 7, 2016

**Performing Laboratory:**

**Analytical Services:**

Impossible Foods  
525 Chesapeake Dr.  
Redwood City, CA, 94063

**Project Identification Number:**

Impossible Foods Study Number IF-43166

# IMPOSSIBLE

## GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

Soy Leghemoglobin Preparation

This analysis was conducted in a non-GLP certified facility. Method validation and sample analysis were performed and documented according to GLP. Characterization of reference substance was documented according to GLP.

(b) (6)

Principal Investigator: \_\_\_\_\_

Date: 12/7/2016

Name of Signer: Pavel A. Aronov, PhD

Name of Company: Impossible Foods

**IMPOSSIBLE™**

**SIGNATURE**

Soy Leghemoglobin Preparation

I, the undersigned, declare that the methods, results and data contained in this report faithfully reflect the procedures used and raw data collected during the study.

Pavel A. Aronov, PhD  
Principal Scientist  
Impossible Foods

(b)  
(6)

Date

12/7/2016

# IMPOSSIBLE<sup>®</sup>

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# IMPOSSIBLE™

## STUDY INFORMATION

Protocol No.:	IF-43166
Test Substance:	Soy Leghemoglobin Preparation Lot/Batch #: PP-PGM2-16-088-301
Physical Description:	Red/Brown Powder
Date Test Substance Received:	October 11, 2016 and October 25, 2016
PSL Reference Nos.:	160720-5R
PSL Study Number:	43166
Sponsor:	Impossible Foods, Inc.
Dates of Analysis:	
Analytical Principal Investigator:	Pavel A. Aronov, PhD
Primary Chemists:	Puja Agrawal, MS Rachel Fraser, PhD

# IMPOSSIBLE

## 1. SUMMARY

This report presents the dietary mixture and test substance analysis phase of PSL Study Number 43166: Soy Leghemoglobin Preparation: A 28-DAY DIETARY STUDY IN RATS. Samples were collected at various intervals for neat test substance stability (NT), stability in the dietary mixture (SA), homogeneity (HO), and concentration verification (CV) and transferred to the Analytical laboratory of Impossible Foods. This method was validated in terms of linearity, specificity, precision, and accuracy. All samples were received frozen and were maintained frozen prior to extraction.

Samples (BO – Both Male and Female diets, MA – Male diet, FE – Female diet):

Neat test substance for Stability: Week 1, Week 3, and Week 4

NT 1 A  
NT 2 A  
NT 3 A

Dietary mixture samples for Stability (Days 0, 4, 7 and 10):

SA0 1A BO	SA7 17A FE	SA0 6A MA
SA4 8A BO	SA10 24A FE	SA4 13A MA
SA7 15A BO	SA0 4A MA	SA7 20A MA
SA10 22A BO	SA4 11A MA	SA10 27A MA
SA0 2A MA	SA7 18A MA	SA0 7A FE
SA4 9A MA	SA10 25A MA	SA4 17A FE
SA7 16A MA	SA0 5A FE	SA7 21A FE
SA10 23A MA	SA4 12A FE	SA10 28A FE
SA0 3A FE	SA7 19A FE	
SA4 10A FE	SA10 26A FE	

Initial (Day 0) Dietary Samples for Concentration Verification: and Homogeneity (T = top, M = middle, B = bottom):

HO 1 A M BO	HO 11 A T FE
HO 2 A T MA	HO 12 A M FE
HO 3 A M MA	HO 13 A B FE
HO 4 A B MA	HO 14 A T MA
HO 5 A T FE	HO 15 A M MA
HO 6 A M FE	HO 16 A B MA
HO 7 A B FE	HO 17 A T FE
HO 8 A T MA	HO 18 A M FE
HO 9 A M MA	HO 19 A B FE
HO 10 A B MA	

Intermediate (Day 7) Dietary Samples for Concentration Verification:

CV 1 A BO	CV 4 A MA
CV 2 A MA	CV 5 A FE
CV 3 A FE	CV 6 A MA

# IMPOSSIBLE

CV 7 A FE

Final (Day 21) Dietary Samples for Concentration Verification:

CV 8 A BO  
CV 9 A MA  
CV 10 A FE  
CV 11 A MA  
CV 12 A FE  
CV 13 A MA  
CV 14 A FE



# IMPOSSIBLE

## 2. PROCEDURE FOR THE DETERMINATION OF SOY LEGHEMOGLOBIN PREPARATION BY HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC)

### A. Reference Standard

Note: The neat test substance was used as the reference standard. No purity correction was applied. Results were reported as test substance concentration (versus active ingredient concentration).

Name: Soy Leghemoglobin Preparation  
Lot/Batch #: PP-PGM2-16-088-301  
PSL No.: 160720-5R  
Purity: 48.82%  
Exp. Date: March 2017  
Supplied by: Impossible Foods, Inc

### B. Method Validation

Linearity, system suitability, specificity, precision, and accuracy (spike recovery) determinations were performed prior to analysis.

Stock Standard Solution: A standard solution was prepared by weighing 0.1 grams of reference standard into a 50 mL polypropylene tube, diluting with 25 g of Lysis Reagent, shaking for 60 minutes, and mixing well.

2.B.1 Detector Linearity: The linearity of detector response was assessed using reference substance solutions targeted to bracket the expected concentrations for the analyte.

Linearity Standard Preparation: Five standard solutions with concentrations ranging from approximately 0.125 to 2 mg/mL (LIN 1 - LIN 5) were prepared by preparing individual dilutions of the stock standard solution in Lysis Reagent by weight and mixing well. Linearity solution shelf life is 3 days at 4C or 12 months at -80C.

Linear regression of the analyte peak gave coefficients of determination ( $R^2$ ) of 0.9977 - 1.0000, which were considered acceptable.

2.B.2 System Suitability: Five replicate injections of the mid-point linearity solution (LIN 3-1) produced relative standard deviations for this study of 0.2% - 1.5% for peak response and 0.0% - 0.2% for retention time.

2.B.3 Specificity: Specificity was demonstrated by the absence of significant interferences in replicate linearity (LIN 1-A) and control feed samples (HO 1 AM-1). Background was <5% of the lowest standard signal.

2.B.4 Accuracy (Spike recovery) and Precision:

Duplicate QC stock solutions were prepared by weighing approximately 0.5 gram of a control sample (HO 1 AM) into separate 50 mL polypropylene centrifuge tubes, pipetting 1.25 mL (QC Low) or 2.5 mL (QC High) of STD1 stock standard solution, and adding 8.75 mL (QC High) or 7.5 mL (QC High) of Lysis Reagent into each tube. Each mixture was capped and placed in a mechanical shaker for 60 minutes. The solutions were allowed to settle for 30 minutes and filtered using a 0.2µm 96-well filter

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plates. Filtrate was collected in 96-well conical bottom plate for HPLC analysis.

Chromatography of the working QC solutions demonstrated accuracy (% recovery) to be 88.2% - 97.7% for QC Low and 87.2 - 92.6% for QC High. The %RSD was 0.3% - 3.7% for QC Low and 0.6% - 1.2% for QC High for precision.

### C. Analysis by High Performance Liquid Chromatography (HPLC)

2.C.1 Standard Preparation: The linearity solutions were injected with every sequence and were used for interpolation of assay results. An example result is shown in 2.B.1.

Note: All diet samples were removed from the freezer and allowed to equilibrate to room temperature before weighing.

2.C.2 Test Sample Preparation for Neat Test Substance: Samples were prepared in triplicate. Approximately 0.1 g of the test substance was weighed into 50 ml. polypropylene centrifuge tubes, diluted with 25 g lysis reagent, and placed in a mechanical shaker for 60 minutes. Secondary dilutions were performed as necessary. Samples were mixed well and filtered using a 0.2µm 96-well filter plates. Filtrate was collected in 96-well conical bottom plate for HPLC analysis. Filtrate shelf life is 3 days at 4C or 12 months at -80C.

2.C.3 Sample Preparation for Dietary Samples: Each sample was prepared in triplicate. Approximately 0.5 g of a sample was weighed into a 50 ml. polypropylene centrifuge tube and diluted with Lysis Reagent as necessary (higher concentration samples had a higher dilution). The solution was capped and placed in a mechanical shaker for 60 minutes. The solutions were allowed to settle for 30 minutes and filtered using a 0.2µm 96-well filter plates. Filtrate was collected in 96-well conical bottom plate for HPLC analysis. Filtrate shelf life is 3 days at 4C or 12 months at -80C.

2.C.4 Analysis: At the beginning of the analysis, the instrument was equilibrated until it gave a stable, consistent baseline. The standards and samples were injected at consistent time intervals in order to maintain a steady baseline. A solvent blank and standards were run; all samples were injected in singlet.

2.C.5 Calculations: Results were determined as follows:

$$\text{Calculated Conc. (mg/g)} = \frac{\text{Peak Area} - \text{Intercept}}{\text{Slope}}$$

$$\text{Dose Conc. (ppm)} = \frac{\text{Calc. Conc. (mg/g)} \times \text{Extraction Buffer Wt. (g)} \times 1000}{\text{Sample weight (g)}}$$

$$\text{Theoretical Spike Conc. (mg/g)} = \frac{\text{Wt. of Std. (g)}}{\text{Extraction Buffer Wt. (g)}} \times \text{Std. Conc. (mg/g)}$$

$$\text{Final Conc. (mg/g)} = \text{Theoretical Spike Conc. (mg/g)} \times \text{Wt. of Sample Aliquot (g)} / \text{Final Wt (g)}$$

$$\% \text{ Recovery} = \frac{\text{Calc. Conc. (mg/g)}}{\text{Final Conc. (mg/g)}} \times 100$$

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$$\% \text{ Signal / Background} = \frac{\text{Avg. LIN. L-A. Area response}}{\text{Avg. Control area response}} \times 100$$

$$\% \text{ Target} = \text{Dose Conc. (ppm)} / \text{Corrected Dose Level (ppm)} \times 100$$

### 3. RESULTS

A summary of the analytical chemistry results is presented in Table 1A-D. HPLC operating conditions are presented in Table 2. The analytical method passed all validation parameters (linearity, system suitability, specificity, precision, and accuracy) and results are reported in Table 3. Detailed results of stability analysis, homogeneity analysis, and concentration verification are presented in Tables 4-5. Chromatograms are maintained in the raw data but were not included in this report.

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**TABLE 1A: CHEMICAL ANALYSIS RESULTS**

**Results for Neat Test Substance Stability Samples**

Sampling Day	Measured Recovery (%)	% Change <sup>1</sup>	Overall Stability (%)
Day 0 (Initial)	94.96%	0.00%	100.00%
Day 14 (Middle)	95.29%	0.35%	100.35%
Day 21 (Final)	90.88%	-4.30%	95.70%

<sup>1</sup>  $\frac{\text{Final Sample} - \text{Initial Sample}}{\text{Initial Sample}} \times 100$

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**TABLE 1B: CHEMICAL ANALYSIS RESULTS**

Results for Dietary Stability of Initial Samples

Day <sup>1</sup>	Group	Target Concentration (ppm)	Measured Concentration (ppm)	% of Target <sup>2</sup>
0	1 (BO)	0	ND	NA
	2 (M)	4373	4508	103.08%
	2 (F)	4711	4645	98.61%
	3 (M)	8746	7951	90.91%
	3 (F)	9422	9034	95.89%
	4(M)	13118	12265	93.50%
	4(F)	14133	12808	90.62%
4	1 (BO)	0	ND	NA
	2 (M)	4373	4207	96.20%
	2 (F)	4711	4471	94.90%
	3 (M)	8746	8238	94.19%
	3 (F)	9422	8918	94.65%
	4(M)	13118	12097	92.22%
	4(F)	14133	13191	93.33%
7	1 (BO)	0	ND	NA
	2 (M)	4373	4202	96.09%
	2 (F)	4711	4468	94.84%
	3 (M)	8746	8200	93.76%
	3 (F)	9422	8728	92.63%
	4(M)	13118	12423	94.70%
	4(F)	14133	13547	95.85%
10	1 (BO)	0	ND	NA
	2 (M)	4373	3968	90.74%
	2 (F)	4711	4693	99.63%
	3 (M)	8746	8453	96.65%
	3 (F)	9422	8836	93.78%
	4(M)	13118	12825	97.77%
	4(F)	14133	13762	97.38%

NA - Not Applicable; ND - Not Detected

<sup>1</sup> Days relative to the initial diet preparation.

<sup>2</sup> % of Target = Measured Conc. (ppm) / Target Conc. (ppm) x 100

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**TABLE 1C: CHEMICAL ANALYSIS RESULTS**

**Results for Homogeneity of Dietary Preparations**

Day <sup>1</sup>	Group	Sample Location	Target Concentration (ppm)	Measured Concentration (ppm)	% of Target <sup>2</sup>	Average % of Target	RSD (%)
0	1 (BO)	Middle	0	ND	NA	NA	NA
	2 (M)	Top	4373	4302	98.38%	95.87%	2.92%
		Middle		4061	92.86%		
		Bottom		4215	96.38%		
	2 (F)	Top	4711	4853	103.01%	98.01%	4.77%
		Middle		4583	97.28%		
		Bottom		4416	93.74%		
	3 (M)	Top	8746	8636	98.74%	95.40%	3.09%
		Middle		8145	93.13%		
		Bottom		8250	94.33%		
	3 (F)	Top	9422	9669	102.62%	97.71%	5.50%
		Middle		9284	98.53%		
		Bottom		8666	91.98%		
	4 (M)	Top	13118	12226	93.20%	97.85%	5.24%
		Middle		13558	103.35%		
		Bottom		12724	97.00%		
	4 (F)	Top	14133	14567	103.07%	98.64%	5.57%
		Middle		14183	100.35%		
		Bottom		13072	92.49%		

NA = Not Applicable; ND = Not Detected

<sup>1</sup> Day relative to initial dietary preparation.

<sup>2</sup> % of Target = Measured Conc. (ppm) / Target Conc. (ppm) x 100.

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**TABLE 1D: CHEMICAL ANALYSIS RESULTS**  
Results for Concentration Verification of Dietary Preparations

Day <sup>1</sup>	Group	Target Concentration (ppm)	Measured Concentration (ppm)	% of Target <sup>2</sup>
0 <sup>3</sup>	1 (BO)	0	ND	NA
	2 (M)	4373	4061	92.86%
	2 (F)	4711	4583	97.28%
	3 (M)	8746	8145	93.13%
	3 (F)	9422	9284	98.53%
	4(M)	13118	13558	103.35%
	4(F)	14133	14183	100.35%
7	1 (BO)	0	ND	NA
	2 (M)	6093	6158	101.06%
	2 (F)	5824	5326	91.45%
	3 (M)	12318	12189	98.96%
	3 (F)	11664	11408	97.81%
	4(M)	18362	19409	105.70%
	4(F)	17567	17238	98.13%
21	1 (BO)	0	ND	NA
	2 (M)	7407	6906	93.24%
	2 (F)	5925	5498	92.80%
	3 (M)	14727	14292	97.05%
	3 (F)	12901	12612	97.76%
	4(M)	21943	20786	94.73%
	4(F)	19281	18829	97.65%

NA = Not Applicable; ND = Not Detected

<sup>1</sup> Days relative to the initial diet preparation.

<sup>2</sup> % of Target = Measured Conc. (ppm) / Target Conc. (ppm) x 100

<sup>3</sup> As part of the homogeneity analysis.

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**TABLE 2: HPLC OPERATING CONDITIONS**

<b>Instrument</b>		Agilent 1100 Series HPLC System, with DAD	
<b>Column</b>		Waters Acquity xBridge BEH125 SEC, 7.8 x 150 mm ID 3.5µm	
<b>Flow rate (mL/min)</b>		0.86	
<b>Injection Volume (µL)</b>		25	
<b>Wavelength (nm)</b>		405	
<b>Column Temperature (°C)</b>		Ambient	
<b>Tray Temperature (°C)</b>		4	
<b>Run time (min)</b>	<b>Flow rate (ml/min)</b>	<b>HPLC-Grade Water (%)</b>	<b>50 mM Potassium Phosphate pH 7.4, 5 mM Sodium Chloride (%)</b>
0-14.00 min	0.86	0	100
14.01-19.00 min	0.86	100	0
19.01 to 30.00 min	0.86	0	100



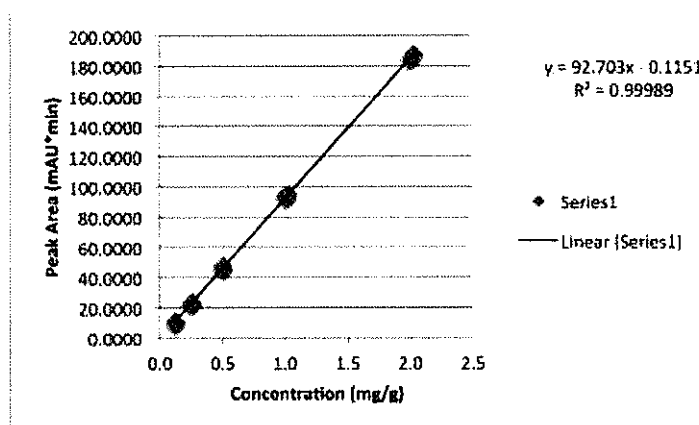
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**TABLE 3: METHOD VALIDATION RESULTS**

Linearity

(Analyzed on 11/17/2016)

Sample ID	Peak Area	Theoretical Concentration (mg/g)
Lin 1	10.5743	0.1236
	10.7110	0.1239
Lin 2	23.4604	0.2572
	22.9334	0.2509
Lin 3	47.5942	0.5066
	46.4874	0.4962
Lin 4	94.8130	1.0224
	93.6001	0.9964
Lin 5	187.6864	2.0265
	184.2777	1.9985
<b>Slope:</b>		92.7032
<b>Intercept:</b>		-0.1151
<b>Correlation Coefficient (r):</b>		0.9999



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**TABLE 3 (cont.): METHOD VALIDATION RESULTS**

System Suitability

(Analyzed on 11/17/2016)

Sample ID	Theoretical Conc. (mg/g)	Retention time (min)	Peak Area
LIN 3-1	0.4962	4.1680	45.1002
		4.1682	44.9289
		4.1687	44.7097
		4.1703	44.3757
		4.1688	44.2105
<b>Average</b>		4.1688	44.6650
<b>STDEV</b>		0.0009	0.3713
<b>%RSD</b>		0.0%	0.8%

Accuracy and Precision

(Analyzed on 11/17/2016)

Sample Name	Theoretical Conc. (mg/g)	Peak Area	Calculated Conc. (mg/g)	% Recovery	Average % Recovery (SD / %RSD)
QC Low	0.5012	45.1037	0.4878	97.3%	97.0% (0.3% / 0.3%)
		44.9771	0.4864	97.0%	
	0.5062	45.4857	0.4919	97.2%	
		45.2369	0.4892	96.6%	
QC High	1.0082	87.1050	0.9409	93.3%	92.6% (0.7% / 0.8%)
		86.7802	0.9373	93.0%	
	1.0086	86.1798	0.9309	92.3%	
		85.6498	0.9252	91.7%	
$y = 92.7032 - 0.1151$					

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**TABLE 3 (cont): METHOD VALIDATION RESULTS**

Specificity (Analyzed on 10/17/2016)

	Peak Area	Specificity
	11.1192	NA
LIN 1-A	11.7481	
HO 1 AM-1	ND	
HO 1 AM-2	ND	
HO 1 AM-3	ND	

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**TABLE 4: NEAT TEST SUBSTANCE STABILITY ANALYSIS**

Analyzed on 10/27/2016

Day <sup>1</sup>	Sample Name	Sample Weight (g)	Final Conc. (mg/g)	Peak Area	Calculated Conc. (mg/g)	% Recovery	Avg. % Recovery	SD / %RSD
0	NT 1 A	0.3017	0.4974	45.3436	0.4738	95.25%	94.96%	0.0036 / 0.38%
		0.0998	0.4888	44.2652	0.4622	94.55%		
		0.3011	0.4960	45.1470	0.4717	95.08%		
14	NT 2 A	0.1026	0.5017	45.6401	0.4770	95.08%	95.29%	0.0053 / 0.55%
		0.1031	0.5016	45.5543	0.4760	94.91%		
		0.1008	0.4886	44.8581	0.4686	95.89%		
21	NT 3 A	0.1039	0.5087	43.0057	0.4487	88.20%	90.88%	0.0245 / 2.70%
		0.1031	0.5132	45.6832	0.4774	93.02%		
		0.1047	0.5181	45.3258	0.4736	91.41%		
$y = 93.1257 + 1.2237$								

<sup>1</sup> Days relative to the initial diet preparation.

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**TABLE 5: DIETARY MIXTURE SAMPLE ANALYSIS**

Study Day 0 (HO HO MA Analyzed on 10-17-2016, HO FE Analyzed on 10-19-2016)

Sample ID	Sample Wt. (g)	Lysis Reagent Wt. (g)	Dose Level (ppm)	Peak Area	Calc. Conc. (mg/L)	Dose Conc. (ppm)	Average (ppm)	%RSD	% Target	% Target Average	% Target between the strata (Avg. / RSD)
HO 1 A M-1	0.5071	5.0400	0	ND	NA	NA	NA	NA	NA	NA	NA
HO 1 A M-2	0.5011	5.0178		ND	NA	NA					
HO 1 A M-3	0.5091	5.0355		ND	NA	NA					
HO 2 A T-1	0.5221	5.0905	4372	44,3192	0.4360	4490	4302	3.00%	101.75%	98.89%	95.87%
HO 2 A T-2	0.5204	5.0573		42,4804	0.4405	4191			97.53%		
HO 2 A T-3	0.5051	5.0814		40,9036	0.4241	4267			97.57%		
HO 3 A M-1	0.5071	5.0640	4373	39,6148	0.4100	4111	4061	1.88%	94.62%	92.89%	95.87%
HO 3 A M-2	0.5298	5.0759		40,6607	0.4148	3973			91.23%		
HO 3 A M-3	0.5076	5.0688		39,6398	0.4164	4098			93.71%		
HO 4 A B-1	0.4943	5.0630	4374	38,1794	0.3970	4066	4215	4.90%	92.88%	96.38%	95.87%
HO 4 A B-2	0.5022	5.0455		*	*	3533			*		
HO 4 A B-3	0.5122	5.0825		42,4029	0.4197	4161			99.78%		
HO 5 A T-1	0.5277	5.0770	4711	47,1590	0.4680	4695	4653	2.87%	99.65%	100.01%	96.01%
HO 5 A T-2	0.5022	5.0649		47,6758	0.4912	4928			104.13%		
HO 5 A T-3	0.4967	5.0461		46,8567	0.4829	4895			99.63%		
HO 6 A M-1	0.5032	5.0606	4711	45,7853	0.4720	4693	4593	3.04%	93.93%	97.28%	96.01%
HO 6 A M-2	0.5130	5.0335		43,7029	0.4369	4429			93.93%		
HO 6 A M-3	0.4991	4.9870		44,9224	0.4653	4629			98.20%		
HO 7 A B-1	0.4997	5.0360	4711	43,7868	0.4517	4553	4416	3.15%	96.64%	91.31%	96.01%
HO 7 A B-2	0.4896	5.0934		40,0276	0.4136	4267			90.57%		
HO 7 A B-3	0.5034	5.0170		43,0629	0.4444	4429			94.02%		

HO and MA:  $s = 94.0549\%$ ,  $t = 1.0415$  FE:  $s = 90.6424\%$ ,  $t = 0.7744$

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TABLE 5 (cont.) INDIVIDUAL SAMPLE ANALYSES

Study Day 0 Cont. (HU BO MA Analyzed on 10/17/2016, HO FE Analyzed on 10/19/2016)

Sample ID	Sample Wt. (g)	Lyso Reagent Wt. (g)	Dose Level (ppm)	Peak Area	Calc. Conc. (mg/g)	Dose Conc. (ppm)	Average (ppm)	%RSD	% Target	% Target Average	% Target between the stats (Avg./RSD)	
HO 8 A T-1	0.5344	10.1522	8748	31.1902	0.5305	6459	6814	4.97%	73.73%	77.01%	80.45% 4.03%	
HO 8 A T-2	0.5037	10.1210		33.2054	0.5429	6671						
HO 8 A T-3	0.5127	10.0918		35.0665	0.5617	7123						
HO 9 A M-1	0.5330	10.0437		34.0808	0.5553	6795	6986	4.55%	77.02%			
HO 9 A M-2	0.5317	10.0362		34.1460	0.5500	6777						
HO 9 A M-3	0.5179	10.1304		30.7454	0.5172	7912						
HO 10 A B-1	0.5118	10.1708		7153	37.2761	0.5882	7625	7153	7.08%			87.18%
HO 10 A B-2	0.4923	10.0657			36.3183	0.5700	7607					
HO 10 A B-3	0.5069	10.1429			34.1700	0.5522	6784					
HO 11 A T-1	0.4995	10.1681	8491		39.6039	0.6093	8133	8491	5.67%	88.44%		
HO 11 A T-2	0.4862	10.0792			36.3279	0.6065	8092					
HO 11 A T-3	0.5053	10.0604			44.0646	0.6546	9050					
HO 12 A M-1	0.5223	10.0621			8423	40.6492	0.6301	8678	8423	3.70%	92.10%	
HO 12 A M-2	0.4906	10.0948				40.1411	0.6148	8335				
HO 12 A M-3	0.5129	10.0411				39.8711	0.6121	8007				
HO 13 A B-1	0.5200	10.0168		7854		41.4060	0.6276	8239	7854	3.83%	87.44%	
HO 13 A B-2	0.5021	10.0327				38.2093	0.6052	7912				
HO 13 A B-3	0.5066	10.0746				35.6744	0.6045	7937				
HO 14 A T-1	0.5172	10.0907	8776			40.1873	0.6199	8327	8776	7.04%	88.78%	
HO 14 A T-2	0.5146	10.1351				34.7101	0.5579	10328				
HO 14 A T-3	0.5112	10.0663				33.2306	0.5319	6782				
HO 15 A M-1	0.5110	10.1496			10309	33.8490	0.5286	10028	10309	0.88%	98.19%	
HO 15 A M-2	0.5113	10.0406				34.3287	0.5329	10886				
HO 15 A M-3	0.4932	10.1133				32.4473	0.5199	10211				
HO 16 A B-1	0.5085	10.0909		10417		33.7001	0.5472	10283	10417	1.80%	98.43%	
HO 16 A B-2	0.4913	10.1271				32.6994	0.5346	10062				
HO 16 A B-3	0.5239	10.2106				35.4266	0.6026	11826				

HO 16 A MA 1 - 40.0945 - 11110 FE 3 - 88.6341 - 0.7746

# IMPOSSIBLE

**TABLE 5 (cont.) INDIVIDUAL SAMPLE ANALYSES**

Study Day 0 Cont. (HO BO MA Analyzed on 10/17/2016, HO FE Analyzed on 10/19/2016)

Sample ID	Sample Wt. (g)	Lysis Reagent Wt. (g)	Dose Level (ppm)	Peak Area	Calc. Conc. (mg/g)	Dose Conc. (ppm)	Average (ppm)	%RSD	% Target	% Target Average	% Target between the strata
HO 17 A T-1	0.4173	15.0543	14133	38.2879	0.3060	11529	11384	2.21%	81.51%	80.58%	79.32% / 1.30%
HO 17 A T-2	0.5150	15.0514		39.5201	0.3061	11529			81.56%		
HO 17 A T-3	0.4957	15.0079		35.3673	0.3064	11093			78.69%		
HO 18 A M-1	0.5250	15.1448		39.6923	0.3798	11357	11197	3.47%	78.94%	79.22%	
HO 18 A M-2	0.5000	15.1290		34.5308	0.3579	10830			76.61%		
HO 18 A M-3	0.4911	15.1296		36.3798	0.3707	11604			82.11%		
HO 19 A B-1	0.5112	15.1035		38.9280	0.4025	11892	11074	6.49%	84.14%	78.15%	
HO 19 A B-2	0.5204	15.0779		34.5300	0.3576	10788			76.51%		
HO 19 A B-3	0.4928	15.0226		33.3311	0.3496	10542			74.49%		

BO and MA:  $y = 0.411599x + 1.0411$  FE:  $y = 0.64314x - 0.7748$

NA = Not Applicable; ND = Not Detected

\* Excluded due to non-trending result

Cells shaded in gray were re-analyzed on 11/8/2016 and 11/9/2016 due to low signal.

# IMPOSSIBLE

TABLE 5 (cont.) INDIVIDUAL SAMPLE ANALYSES

Day 0 Preparation (HOMA Analyzed on 11/8/2016, HOTE Analyzed on 11/9/2016)

Sample ID	Sample Wt. (g)	Lyso-Reagent Wt. (g)	Dose Level (ppm)	Peak Area	Peak Conc. (mg/g)	Dose Conc. (ppm)	Average (ppm)	% RSD	% Target	% Target Average	% Target between the strata (Avg. ± RSD)
HO10A T-1	0.5044	0.01902	8740	41.3494	0.4069	8671	8636	5.00%	99.14%	98.74%	95.07% ± 2.67%
HO10A T-2	0.5037	0.01210		53.1624	0.4301	8629					
HO10A T-3	0.5127	0.0015		99.9904	0.4160	8107					
HO10A M-1	0.5240	0.0477		41.6205	0.4118	8118					
HO10A M-2	0.5217	0.0362		38.9849	0.4014	7728					
HO10A M-3	0.5177	0.01904		41.1521	0.4286	8090					
HO10A B-1	0.5116	0.03298		41.2864	0.4298	8037					
HO10A B-2	0.4921	0.00857		41.1725	0.4280	8702					
HO10A B-3	0.5299	0.03429		38.4383	0.3996	7863					
HO11A F-1	0.5095	0.01091		9222	55.5444	0.4798			9688		
HO11A F-2	0.5064	0.0092	43.9859		0.4592	9139					
HO11A F-3	0.5053	0.0091	48.8991		0.5111	10180					
HO11A M-1	0.5223	0.0624	47.6973		0.4926	9402					
HO11A M-2	0.4936	0.0348	43.8960		0.4578	9421					
HO11A M-3	0.5129	0.0411	44.2416		0.4566	8938					
HO11A B-1	0.5200	0.0188	44.8412		0.4684	9225					
HO11A B-2	0.5031	0.0187	41.1713		0.4390	8698					
HO11A B-3	0.5066	0.0086	40.5455		0.4322	8085					
HO11A T-1	0.5172	0.0007	40.3516		0.4302	12235					
HO12A F-2	0.5146	0.0335	6118	45.7543	0.4784	14070	13261	7.00%	105.26%	101.08%	100.48% ± 3.28%
HO12A F-3	0.5112	0.0067		40.8994	0.4372	11474					
HO12A M-1	0.5116	0.0486		44.9781	0.4698	13912					
HO12A M-2	0.5113	0.0486		40.7889	0.4568	13444					
HO12A M-3	0.4942	0.0112		41.7957	0.4385	13347					
HO12A B-1	0.5085	0.0069		40.9314	0.4264	12604					
HO12A B-2	0.4912	0.0121		40.0790	0.4172	12846					
HO12A B-3	0.5231	0.0106		41.9863	0.4377	12723					

$$y = 0.1257x + 1.237$$



**IMPOSSIBLE**

**TABLE 5 (cont.) INDIVIDUAL SAMPLE ANALYSES**

Study Day 0 Cont. (HO MA Analyzed on 11/8/2016, HO FE Analyzed on 11/9/2016)

Sample ID	Sample Wt. (g)	Lysis Reagent WL (g)	Dose Level (ppm)	Peak Area	Calc. Conc. (mg/g)	Dose Conc. (ppm)	Average (ppm)	%RSD	% Target	% Target Average	% Target between the strata
HO 17 A T-1	0.5173	15.0543	14133	47.8980	0.5009	14982	14967	0.52%	103.18%	103.15%	98.64% / 4.57%
HO 17 A T-2	0.5170	14.9814		47.9792	0.5021	14985			103.44%		
HO 17 A T-3	0.4957	15.0079		45.9765	0.4704	14515			102.70%		
HO 18 A M-1	0.5136	15.1426		26.9848	0.2814	14434	14381	1.7%	98.66%		
HO 18 A M-2	0.5000	15.1290		41.1394	0.4298	13944			100.37%		
HO 18 A M-3	0.4911	15.1298		34.0386	0.3600	13171			96.89%		
HO 19 A B-1	0.5112	15.1045		31.3844	0.3335	13093	13672	4.71%	92.40%		
HO 19 A B-2	0.5081	15.0779		31.5615	0.3332	13060			98.16%		
HO 19 A B-3	0.4928	15.0228		52.2859	0.5468	17263					

Cells shaded in gray were re-analyzed on 12/05/2016 due to high %RSD.

# IMPOSSIBLE

**TABLE 5 (cont.) INDIVIDUAL SAMPLE ANALYSES**

Day 0 Preparation (SA 10 MA Analyzed on 10/21/2016, SA FE Analyzed on 10/21/2016)

Sample ID	Sample Wt. (g)	Lysis Reagent Wt. (g)	Dose Level (ppm)	Peak Area	Calc. Conc. (mg/mL)	Dose Conc. (ppm)	Average (ppm)	%RSD	% Target	% Target Average		
SA 0-1 A-1	0.4881	4.8002	11	ND	NA	NA	NA	NA	NA	NA		
SA 0-1 A-2	0.5099	4.8964		ND	NA	NA			NA		NA	NA
SA 0-1 A-3	0.5263	4.9065		ND	NA	NA			NA		NA	NA
SA 4-4 A-1	0.5051	5.0302		ND	NA	NA	NA	NA	NA	NA		
SA 4-4 A-2	0.4814	4.9104		ND	NA	NA			NA		NA	NA
SA 4-4 A-3	0.4865	4.9915		ND	NA	NA			NA		NA	NA
SA 7-13 A-1	0.4909	4.9241		ND	NA	NA	NA	NA	NA	NA		
SA 7-13 A-2	0.5125	4.9267		ND	NA	NA			NA		NA	NA
SA 7-13 A-3	0.4881	4.9249		ND	NA	NA			NA		NA	NA
SA 10-17 A-1	0.5285	4.9491		ND	NA	NA	NA	NA	NA	NA		
SA 10-17 A-2	0.5181	4.9289		ND	NA	NA			NA		NA	NA
SA 10-17 A-3	0.5115	4.9502		ND	NA	NA			NA		NA	NA
-----												
SA 2-9 A-1	0.4849	4.9176	4573	89.5467	0.4119	4395	4207	5.21%	56.14%	96.20%		
SA 2-9 A-2	0.4917	4.9466		37.7824	0.2954	9805			91.20%			
SA 2-9 A-3	0.5098	4.9572		43.1941	0.4325	4426			101.31%			
SA 7-16 A-1	0.4979	4.9791		36.8080	0.4114	4111	4202	2.80%	94.06%	96.69%		
SA 7-16 A-2	0.5013	4.9467		20.2128	0.4211	3155			95.02%			
SA 7-16 A-3	0.5176	4.9378		43.3691	0.4546	4347			99.17%			
SA 10-23 A-1	0.5019	5.0154		38.1195	0.4856	4811	3908	1.56%	93.01%	101.74%		
SA 10-23 A-2	0.5042	4.9810		38.4588	0.4824	3803			91.98%			
SA 10-23 A-3	0.5045	5.0601		56.9339	0.3863	3828			87.54%			

603 and MA v : 04.7074e + 0.3340 FL v : 54.3266e + 0.4291

**IMPOSSIBLE**

**TABLE 5 (cont.) INDIVIDUAL SAMPLE ANALYSES**

Day 0 Preparation Cont. (SA BO MA Analyzed on 10/21/2016, SA FT Analyzed on 10/24/2016)

Sample ID	Sample Wt. (g)	Lysis Reagent Wt. (g)	Dose Level (ppm)	Peak Area	Calc. Conc. (mg/g)	Dose Conc. (ppm)	Average (ppm)	% RSD	% Target	% Target Average
SA 0-1 A-1	0.5300	5.0218	4711	46.1028	0.4863	4697	4645	1.90%	99.70%	98.61%
SA 0-1 A-2	0.5102	4.9069		44.1541	0.4636	4542			96.41%	
SA 0-1 A-3	0.4980	5.0840		44.9286	0.4622	4607			97.71%	
SA 4-10 A-1	0.4907	4.9941		42.3142	0.4411	4324			96.03%	
SA 4-10 A-2	0.5008	4.9927		41.8842	0.4395	4381			93.01%	
SA 4-10 A-3	0.5216	5.0283		42.8206	0.4495	4500			95.63%	
SA 7-17 A-1	0.5180	5.0789		42.8213	0.4490	4347	92.77%	2.43%	95.49%	94.84%
SA 7-17 A-2	0.5057	5.0316		42.8201	0.4489	4388	96.75%			
SA 7-17 A-3	0.5206	5.0191		45.5214	0.4781	4589	100.11%			
SA 10-24 A-1	0.5134	4.9918		46.1834	0.4851	4716	101.19%	5.01%	101.19%	99.63%
SA 10-24 A-2	0.5099	4.9483		47.3341	0.4942	4916	94.41%			
SA 10-24 A-3	0.4980	5.0621		41.5164	0.4175	4348	87.53%			
SA 0-4 A-1	0.5115	10.1250	8748	275.933	0.3942	7699	7448	4.55%	87.23%	85.18%
SA 0-4 A-2	0.4894	10.0948		25.4058	0.3702	7632			80.69%	
SA 0-4 A-3	0.5177	10.0857		34.7139	0.3629	7897			98.41%	
SA 4-18 A-1	0.4999	10.0417		36.6365	0.3780	7532			80.59%	
SA 4-18 A-2	0.5228	10.0884		36.7524	0.3802	7537			84.20%	
SA 4-18 A-3	0.5143	10.0994		35.6883	0.3755	7864			82.04%	
SA 7-18 A-1	0.5131	10.0562		37.9877	0.3880	7419	82.50%	1.80%	84.80%	83.12%
SA 7-18 A-2	0.5058	10.0839		37.7816	0.3880	7419	89.21%			
SA 7-18 A-3	0.5091	10.0272		34.8172	0.3640	7216	86.26%			
SA 10-25 A-1	0.5159	10.1057		37.9867	0.3911	7811	86.26%	6.00%	86.26%	85.06%
SA 10-25 A-2	0.5153	10.1189		33.7181	0.3524	6918	78.11%			
SA 10-25 A-3	0.5203	10.1069		38.2896	0.3828	7824	85.06%			

BC Cont MA: y = 94.7074x - 0.440 PE: y = 94.3266x - 0.4281

# IMPOSSIBLE

**TABLE 5 (cont.) INDIVIDUAL SAMPLE ANALYSES**

Day 0 Preparation Cont. (SA BO MA Analyzed on 10/21/2016, SA FT Analyzed on 10/24/2016)

Sample ID	Sample Wt. (g)	Lysis Reagent Wt. (g)	Dose Level (ppm)	Peak Area	Calc. Conc. (mg/g)	Dose Conc. (ppm)	Average (ppm)	%RND	% Target	% Target Average
SA B-5 A-1	0.4950	10.1258	9422	38.1442	0.3998	8179	7807	11.70%	26.51%	76.49%
SA B-5 A-2	0.5108	10.1349		33.1850	0.3473	6771			71.80%	
SA B-5 A-3	0.5016	10.0224		31.9203	0.3330	6671			70.89%	
SA 4-12 A-1	0.5173	10.1350		39.5034	0.4119	8121	8102	1.77%	86.19%	85.09%
SA 4-12 A-2	0.4902	0.9998		39.2047	0.4111	8235			87.40%	
SA 4-12 A-3	0.5192	10.1180		38.8221	0.4070	7920			84.38%	
SA 7-19 A-1	0.5282	10.0854		39.8413	0.4178	7932	7910	0.77%	84.40%	83.50%
SA 7-19 A-2	0.5253	10.1003		37.4567	0.3923	7839			81.20%	
SA 7-19 A-3	0.4968	10.0567		37.4150	0.3921	7938			84.23%	
SA 10-20 A-1	0.4978	10.1201		37.6717	0.3948	8036	7940	3.05%	85.23%	84.27%
SA 10-20 A-2	0.5281	10.1127		36.7710	0.3853	7660			81.06%	
SA 10-20 A-3	0.4869	10.1092		37.5669	0.3927	8125			86.23%	
SA B-6 A-1	0.5090	15.1480	13118	39.8083	0.4227	9702	10075	3.21%	74.64%	76.80%
SA B-6 A-2	0.4982	15.0103		31.8216	0.3324	6660			76.26%	
SA B-6 A-3	0.5053	15.1707		33.1028	0.3459	6930			79.51%	
SA 4-13 A-1	0.5146	15.0156		34.7374	0.3632	7260	11021	3.08%	81.03%	84.01%
SA 4-13 A-2	0.4811	15.1141		34.9186	0.3690	7239			85.64%	
SA 4-13 A-3	0.5140	15.1230		36.3877	0.3826	7610			89.06%	
SA 7-20 A-1	0.5032	15.0630		34.7190	0.3630	7280	10299	0.25%	82.04%	85.36%
SA 7-20 A-2	0.5221	15.0782		34.3100	0.3582	7054			80.07%	
SA 7-20 A-3	0.4878	15.1031		38.1275	0.4166	8903			73.07%	
SA B-27 A-1	0.5184	15.1240		34.8089	0.3618	7258	10501	10.74%	81.43%	80.74%
SA B-27 A-2	0.5080	15.0712		35.4422	0.3800	7681			81.47%	
SA B-27 A-3	0.5158	15.0530		36.3168	0.3887	7819			80.46%	

BO and MA:  $y = 94.707x + 0.3443$  FF:  $y = 94.3288x + 0.4283$

# IMPOSSIBLE

**TABLE 5 (cont.) INDIVIDUAL SAMPLE ANALYSES**

Day 0 Preparation Cont. ISA BD MA Analyzed on 10/21/2016, SA FE Analyzed on 10/24/2016

Sample ID	Sample Wt. (g)	Lyophil Reagent Wt. (g)	Dose Level (ppm)	Peak Area	Calc. Conc. (mg/L)	Dose Conc. (ppm)	Average (ppm)	%RSD	% Target	% Target Average
SA 0-7 A-1	0.3155	15.0109	14133	30.8174	0.3464	1000	10173	1.28%	70.77%	72.00%
SA 0-7 A-2	0.2956	15.0274		32.7200	0.3443	1000			73.43%	
SA 0-7 A-3	0.2865	15.0077		33.9036	0.3810	10141			71.77%	
SA 4-14 A-1	0.5194	15.0924		31.6399	0.3311	982	9690	1.42%	68.07%	68.63%
SA 4-14 A-2	0.3722	15.0727		31.0092	0.3357	982			69.32%	
SA 4-14 A-3	0.4935	15.1440		30.0940	0.3145	951			66.22%	
SA 7-21 A-1	0.5144	15.1119		31.4223	0.3286	980	9717	7.30%	68.37%	68.76%
SA 7-21 A-2	0.5004	15.1011		29.6912	0.2996	9042			63.68%	
SA 7-21 A-3	0.4928	15.0636		32.6839	0.3421	10437			73.99%	
SA 10-28 A-1	0.5035	15.0944		33.1489	0.3363	1000	9712	3.80%	73.33%	68.72%
SA 10-28 A-2	0.4989	15.1363		31.2634	0.3260	990			70.69%	
SA 10-28 A-3	0.5003	15.0651		36.3659	0.3904	900			84.13%	

BD and MA,  $y = 94.7074x + 0.2440$  FE,  $y = 94.3268x + 0.4280$

NA = Not Applicable; ND = Not Detected

Cells shaded in light gray were re-analyzed on 11/16/2016 and 11/29/2016 due to low signal

Cells shaded in dark gray were re-analyzed on 12/05/2016 due to high %RSD.

# IMPOSSIBLE

**TABLE 5 (cont.) INDIVIDUAL SAMPLE ANALYSES**  
Day 0 Preparation (SA MA Analyzed on 11/29/2016, SA FE Analyzed on 11/16/2016)

Sample ID	Sample Wt. (g)	Lysis Reagent Wt. (g)	Dose Level (ppm)	Peak Area	Calc. Conc. (mg/ml)	Dose Conc. (ppm)	Average (ppm)	%RSD	% Target	% Target Average
SA 8-4 A-1	0.5148	10.0772	8506	16.6329	0.3969	7710	7606	3.07%	88.16%	87.86%
SA 8-4 A-2	0.5072	10.0703		33.7418	0.3503	7222				
SA 8-4 A-3	0.5261	10.0563		39.3638	0.4280	8124				
SA 4-11 A-1	0.5165	10.0730		14.9180	0.3752	7249				
SA 4-11 A-2	0.5129	10.0727		16.3481	0.3691	7786				
SA 4-11 A-3	0.5183	9.9986		14.8752	0.3774	7275				
SA 7-18 A-1	0.5092	10.0576		14.8811	0.3771	7452				
SA 7-18 A-2	0.5045	10.0593		16.1730	0.3910	7935				
SA 7-18 A-3	0.5110	10.0660		15.0720	0.3645	7350				
SA 10-25 A-1	0.5279	9.9713		19.8356	0.4302	8304			7637	
SA 10-25 A-2	0.5085	9.9883	15.1250	0.3621	7322					
SA 10-25 A-3	0.4990	10.0807	15.9542	0.3686	7613					
SA 11-5 A-1	0.4950	10.1238	8422	18.6294	0.4307	8014	8014	0.27%	85.07%	85.06%
SA 11-5 A-2	0.5198	10.1349		10.6642	0.4631	4827				
SA 11-5 A-3	0.5016	10.0224		19.7995	0.4533	9061				
SA 4-17 A-1	0.5175	10.1708		19.8314	0.4541	8689				
SA 4-17 A-2	0.4992	9.9698		19.7481	0.4529	9071				
SA 4-17 A-3	0.5181	10.1190		19.4864	0.4501	8792				
SA 7-19 A-1	0.5289	10.0654		10.2552	0.4582	8719				
SA 7-19 A-2	0.5045	10.0911		17.7233	0.4307	8806				
SA 7-19 A-3	0.4988	10.0567		18.3455	0.4379	8357				
SA 10-26 A-1	0.4976	10.1201		18.3853	0.4387	9308			8836	
SA 10-26 A-2	0.5083	10.1127	18.2140	0.4361	9077					
SA 10-26 A-3	0.4889	10.0992	17.8841	0.4325	8925					

MA : 05.769% 0.493h FE : 0.916h 1.5410

**IMPOSSIBLE**

**TABLE 5 (cont.) INDIVIDUAL SAMPLE ANALYSES**

Day 0 Preparation Cont. (SA MA Analyzed on 11/29/2016, SA FE Analyzed on 11/16/2016)

Sample ID	Sample Wt. (g)	Lysate Reagent Wt. (g)	Dose Level (ppm)	Peak Area	Calc. Conc. (mg/ml)	Dose Conc. (ppm)	Average (ppm)	% RSD	% Target	% Target Average
SA 0-6 A 1	0.5000	15.0264	1:1:10	34.4315	0.3726	10996	11206	1.02%	93.02%	93.41%
SA 0-6 A 2	0.5000	15.1169		34.0543	0.3777	11285				
SA 0-6 A 3	0.5000	15.1013		35.9028	0.3900	11339				
SA 4-11 A 1	0.5000	15.0357		36.3756	0.3951	11687				
SA 4-11 A 2	0.5020	15.0859		37.3620	0.4017	12141				
SA 4-11 A 3	0.5081	15.1276		38.8604	0.4260	12562				
SA 7-20 A 1	0.5012	15.1644		36.7517	0.3971	12032	11423	2.81%	95.47%	94.70%
SA 7-20 A 2	0.5129	15.2045		39.1290	0.4225	12533				
SA 7-20 A 3	0.5024	15.1561		39.0795	0.4219	12712				
SA 10-27 A 1	0.5102	15.1589		37.6042	0.4082	12060				
SA 10-27 A 2	0.5016	15.1416		42.3633	0.4589	13626				
SA 10-27 A 3	0.5031	15.1237		38.7567	0.4183	12581				
SA 0-7 A 1	0.5135	15.0169	1:1:11	36.3210	0.4153	12099	11004	1.06%	91.85%	91.61%
SA 0-7 A 2	0.4926	15.0274		38.1151	0.4174	11564				
SA 0-7 A 3	0.5265	15.0927		39.9805	0.4356	13060				
SA 4-14 A 1	0.5194	15.0924		40.0184	0.4361	12751				
SA 4-14 A 2	0.5122	15.0737		40.0105	0.4358	12415				
SA 4-14 A 3	0.4935	15.1429		36.3888	0.4205	12803				
SA 7-21 A 1	0.5144	15.1119		40.2469	0.4384	13487	11517	5.91%	101.80%	95.90%
SA 7-21 A 2	0.5084	15.1011		37.6699	0.4217	12780				
SA 7-21 A 3	0.4928	15.0646		41.3654	0.4307	14588				
SA 10-28 A 1	0.5035	15.0944		39.7743	0.4242	13016				
SA 10-28 A 2	0.4888	15.1461		41.4108	0.4375	14318				
SA 10-28 A 3	0.5033	15.0951		37.8841	0.4226	13051				

MA: y = 95.5869x - 0.4936 FE: y = 91.1622x - 1.6190

Cells shaded in gray were re-analyzed on 12/1/2016 due to low signal

# IMPOSSIBLE

**TABLE 5 (cont.) INDIVIDUAL SAMPLE ANALYSES**  
Day 0 Preparation (SA/MA Analyzed on 12/01/2016)

Sample ID	Sample Wt. (g)	Lysis Reagent Wt. (g)	Dose Level (ppm)	Peak Area	Calc. Conc. (mg/mL)	Dose Conc. (ppm)	Average (ppm)	%RSD	% Target	% Target Average
SA 4 11 A.1	0.5165	10.0123	N766	37.2215	0.4105	827.1	828	1.3%	91.16%	91.16%
SA 4 11 A.2	0.5129	10.0127		39.9241	0.4402	864.5				
SA 4 11 A.3	0.5183	9.9986		38.0522	0.4196	839.5				
SA 7 18 A.1	0.5092	10.0556		37.0347	0.4084	816.7	8200	2.41%	96.16%	93.76%
SA 7 18 A.2	0.5045	10.0591		38.3383	0.4227	8428				
SA 7 18 A.3	0.5119	10.0360		37.4918	0.4115	8106				
SA 10 25 A.1	0.5220	9.9713		41.8285	0.4611	879.3	8433	4.05%	92.74%	96.65%
SA 10 25 A.2	0.5085	9.9835		37.4032	0.4124	810.1				
SA 10 25 A.3	0.4999	10.0307		38.1735	0.4211	846.1				
SA 0 6 A.1	0.5092	15.0268	12418	37.0226	0.4084	816.7	12263	1.5%	94.71%	93.90%
SA 0 6 A.2	0.5080	15.1160		37.2147	0.4104	821.3				
SA 0 6 A.3	0.5081	15.1017		38.3277	0.4226	842.9				

Cells shaded in dark gray were re-analyzed on 12/05/2016 due to high % RSD.



# IMPOSSIBLE

TABLE 5 (cont.) INDIVIDUAL SAMPLE ANALYSES

Study Day 7 (Analyzed on 10/27/2016)

Sample ID	Sample Wt. (g)	Lysis Reagent Wt. (g)	Dose Level (ppm)	Peak Area	Calc. Conc. (mg/g)	Dose Conc. (ppm)	Average (ppm)	%RSD	% Target	% Target Average
CV 1 A-1	0.5006	5.0092	0	NID	NA	NA	NA	NA	NA	NA
CV 1 A-2	0.5266	5.0722		NID	NA	NA			NA	
CV 1 A-3	0.5290	5.0776		NID	NA	NA			NA	
CV 2 A-1	0.5062	5.0349	6000	813544	0.0155	6060	6178	1.263	99.56%	101.06%
CV 2 A-2	0.5098	5.0774		779501	0.0202	6177			101.37%	
CV 2 A-3	0.5195	5.0811		663470	0.6170	6211			102.26%	
CV 3 A-1	0.5269	10.0718	9674	276891	0.2638	5395	3126	1.853	92.64%	91.45%
CV 3 A-2	0.5067	10.0522		256998	0.2628	5214			89.51%	
CV 3 A-3	0.503	10.0550		262448	0.2867	5371			92.71%	
CV 4 A-1	0.5057	5.0438	42118	1663607	1.1505	11503	12661	7.20%	81.88%	88.17%
CV 4 A-2	0.5048	5.0435		914003	1.0028	10019			81.34%	
CV 4 A-3	0.5101	5.0790		1043082	1.1011	11000			89.30%	
CV 5 A-1	0.5251	10.0494	11864	512433	0.5386	10501	10276	3.69%	91.66%	86.10%
CV 5 A-2	0.5193	10.0308		302725	0.5207	10186			87.53%	
CV 5 A-3	0.5028	10.0162		477505	0.4998	5981			85.51%	
CV 6 A-1	0.503	15.0755	18662	542243	0.5697	12655	16298	5.26%	92.88%	88.76%
CV 6 A-2	0.5215	15.1264		510149	0.5443	13371			89.71%	
CV 6 A-3	0.5344	15.0972		253718	0.5000	10466			89.09%	
CV 7 A-1	0.5114	15.0686	17567	860187	0.6810	14197	13635	3.89%	80.82%	77.70%
CV 7 A-2	0.5279	15.1903		412578	0.2621	13312			75.78%	
CV 7 A-3	0.5016	15.1680		316094	0.4450	13357			76.60%	

NID - Not Detected, NA - Not applicable.

Cells shaded in gray were re-analyzed on 10/31/2016 due to low signal.

# IMPOSSIBLE

TABLE 5 (cont.) INDIVIDUAL SAMPLE ANALYSES

Study Day 21 (Analyzed on 10/27/2016)

Sample ID	Sample Wt. (g)	Lyso Reagent Wt. (g)	Dose Level (ppm)	Peak Area	Calc. Conc. (mg/g)	Dose Conc. (ppm)	Average (ppm)	%RSD	% Target	% Target Average
CV 1 A-1	0.537	4.9159		ND	NA	NA			NA	
CV 1 A-2	0.507	5.0710	0	ND	NA	NA	NA	NA	NA	NA
CV 1 A-3	0.529	5.0263		ND	NA	NA			NA	
CV 2 A-1	0.5046	5.1853		*	*	*			79.76%	
CV 2 A-2	0.5111	5.0661	7407	66.9236	0.3302	6987	6906	1.65%	91.24%	
CV 2 A-3	0.5022	5.0729		64.1338	0.3258	6926			92.10%	
CV 10 A-1	0.5272	5.1259		55.6407	0.2843	5582			94.21%	
CV 10 A-2	0.526	5.0816	4925	52.7617	0.2634	5329	5398	2.07%	92.80%	
CV 10 A-3	0.5046	5.0102		51.2989	0.2611	5564			94.24%	
CV 11 A-1	0.5187	10.0415		26.4971	0.1324	11282			78.81%	
CV 11 A-2	0.5187	10.0222	14727	31.2759	0.1563	10908	11862	3.24%	73.37%	75.25%
CV 11 A-3	0.5013	10.0588		31.0787	0.1553	11136			75.66%	
CV 12 A-1	0.5128	10.0763		34.5697	0.1728	10623			92.34%	
CV 12 A-2	0.5066	10.1009	12001	36.6799	0.1836	10120	10548	1.79%	78.45%	81.70%
CV 12 A-3	0.5043	10.0722		32.1436	0.1607	10900			84.49%	
CV 13 A-1	0.5023	15.1893		29.1589	0.1457	18811			83.72%	
CV 13 A-2	0.5046	15.1344	21043	57.0598	0.2852	17985	17078	4.66%	82.01%	81.63%
CV 13 A-3	0.5093	15.1257		54.0286	0.2706	17725			79.16%	
CV 14 A-1	0.512	15.2176		47.3386	0.2366	14679			75.01%	
CV 14 A-2	0.5141	15.1611	18281	49.8979	0.2494	12699	13091	2.07%	76.31%	78.27%
CV 14 A-3	0.507	15.0950		49.6208	0.2491	15316			80.28%	

ND - Not Detected, NA - Not applicable.

\* Excluded due to non-trending result

Cells shaded in gray were re-analyzed on 10/31/2016 due to low signal.

# IMPOSSIBLE

**TABLE 5 (cont.) INDIVIDUAL SAMPLE ANALYSES**

Study Days 7 and 21 (Analyzed on 10/31/2016)

Sample ID	Sample Wt. (g)	1.5x8 Reagent Wt. (g)	Dose Level (ppm)	Peak Area	Calc. Conc. (mg/g)	Dose Conc. (ppm)	Average (ppm)	%RSD	% Target	% Target Average
CV 4 A.1	0.5027	5.0750	12114	106.0878	1.1125	11.882	12189	5.76%	92.47%	98.56%
CV 4 A.2	0.5048	5.0415		119.3369	1.2603	13.672			110.87%	
CV 4 A.3	0.5101	5.0990		118.7180	1.2617	13.713			111.58%	
CV 5 A.1	0.5251	10.0494	11664	50.1429	0.6219	11.663	11308	1.99%	110.01%	97.81%
CV 5 A.2	0.5197	10.0928		55.5551	0.5834	11.263			96.73%	
CV 5 A.3	0.5029	10.0462		52.8110	0.5541	11.019			94.69%	
CV 6 A.1	0.503	15.0735	10162	63.6389	0.6701	20.686	10409	4.71%	119.36%	114.91%
CV 6 A.2	0.5214	15.2264		61.7805	0.6501	18.861			110.01%	
CV 6 A.3	0.5344	15.0972		66.3126	0.7011	19.785			117.71%	
CV 7 A.1	0.5114	15.0928	17467	37.3489	0.6249	17.657	17218	1.29%	97.23%	91.68%
CV 7 A.2	0.5273	15.1603		55.3460	0.5812	16.742			91.18%	
CV 7 A.3	0.5016	15.0460		51.0333	0.5469	17.116			93.21%	
CV 11 A.1	0.5187	10.0415	14727	60.6098	0.6769	13.009	15050	3.16%	88.33%	88.01%
CV 11 A.2	0.5187	10.0222		62.5295	0.6583	12.226			86.81%	
CV 11 A.3	0.5015	10.0989		54.1183	0.6753	13.545			91.87%	
CV 12 A.1	0.5128	10.0767	15001	61.0154	0.6655	13.038	12612	1.44%	111.06%	97.76%
CV 12 A.2	0.5086	10.1009		58.2956	0.6128	12.171			94.34%	
CV 12 A.3	0.5043	10.0722		60.0914	0.6421	12.625			97.86%	
CV 13 A.1	0.5023	15.1893	21841	67.1985	0.7385	21.423	20799	3.11%	97.61%	94.73%
CV 13 A.2	0.5046	15.1344		65.8189	0.6996	20.934			94.81%	
CV 13 A.3	0.5095	15.1557		64.2718	0.6765	20.111			91.74%	
CV 14 A.1	0.515	15.2176	19281	59.1638	0.6222	18.984	18429	2.66%	95.39%	97.66%
CV 14 A.2	0.5141	15.1631		60.5584	0.6180	18.729			97.11%	
CV 14 A.3	0.507	15.0669		61.8215	0.6507	19.172			110.47%	

Cells shaded in gray were re-analyzed on 12/05/2016 due to low signal.

# IMPOSSIBLE

**TABLE 5 (cont.) INDIVIDUAL SAMPLE ANALYSES**  
Study Days 0, 7 and 21 (Analyzed on 12/05/2016)

Sample ID	Sample Wt. (g)	Lyso Reagent Wt. (g)	Dose Level (ppm)	Peak Area	Calc. Conc. (mg/g)	Dose Conc. (ppm)	Average (ppm)	%RSD	% Target	% Target Average
CV 11 A 1	0.5292	10.0126		69.2896	0.7601	1490			97.81%	
CV 11 A 2	0.5210	10.0164	1472	66.2234	0.7245	1367	14292	2.61%	94.23%	97.06%
CV 11 A 3	0.5191	10.0179		69.1265	0.7564	1497			99.12%	
HO 4 A B-1	0.5035	5.1077		47.0784	0.5180	5247			110.90%	
HO 4 A B-2	0.5101	5.1543	4373	42.1635	0.4608	4692	4873	6.87%	105.24%	101.43%
HO 4 A B-3	0.5101	5.1601		43.1388	0.4715	4769			109.06%	
CV 9 A 1	0.5014	5.1682		60.8533	0.6637	6862			92.64%	
CV 9 A 2	0.5034	5.1490	5477	67.5114	0.7365	7592	5421	7.05%	101.31%	100.19%
CV 9 A 3	0.5068	5.1549		70.9612	0.7765	7996			105.63%	
HO 10 A B-1	0.5221	10.0138		41.1501	0.4488	4628			98.60%	
HO 10 A B-2	0.5197	10.0045	8746	38.9794	0.4080	792	8231	4.09%	91.37%	94.13%
HO 10 A B-3	0.5081	9.9898		37.8532	0.4136	8131			92.97%	
HO 14 A T-1	0.5159	15.1944		38.5261	0.4217	12419			94.87%	
HO 14 A T-2	0.5051	15.1446	13118	86.3481	0.4089	12561	12226	1.70%	95.79%	93.20%
HO 14 A T-3	0.5083	15.2688		35.6651	0.3895	11697			89.17%	
SA 0 2 A 1	0.5212	5.1675		42.3967	0.4632	4593			105.60%	
SA 0 2 A 2	0.5251	5.1662	4373	41.0131	0.4400	4725	4528	5.68%	108.65%	103.08%
SA 0 2 A 3	0.5184	5.1511		38.7419	0.4231	4337			96.18%	
SA 10 27 A-1	0.5325	15.2288		36.7368	0.4011	11471			87.49%	
SA 10 27 A-2	0.5317	15.2343	13118	31.8336	0.3376	10116	10339	7.49%	77.13%	80.48%
SA 10 27 A-3	0.5304	15.2171		32.8808	0.3537	10809			76.81%	
SA 0 4 A-1	0.5223	9.9531		32.0274	0.4162	7928			93.51%	
SA 0 4 A-2	0.5322	10.0217	8746	35.8961	0.4281	8832	7951	0.57%	91.87%	90.91%
SA 0 4 A-3	0.5051	10.0218		36.5275	0.4006	7011			90.68%	

Cells shaded in gray were excluded from analysis due to high %RSD. Original data was used in analysis.

## **APPENDIX E: OPHTHALMOLOGY**

### **PRODUCT IDENTIFICATION**

Soy Leghemoglobin Preparation

Kristina R. Vygantas, DVM, Diplomate American College of Veterinary Ophthalmologists  
319 Perrineville Rd.  
Robbinsville, NJ 08691  
609.259.8300 (work)

Exam Date: September 23, 2016

Eurofins Study No: ~~160720-SR~~ - 43166 (b) (6)  
PSL No. 160720-SR 11/15/16

44 male and 44 female SD rats were examined. The examination was performed under dim light conditions after pharmacologic mydriasis with 1% tropicamide ophthalmic solution. Both eyes of each animal were examined using slit lamp biomicroscopy and indirect ophthalmoscopy. All animals were all normal on ophthalmic exam and thus, suitable for inclusion in this study.

(b) (6)

Kristina R. Vygantas, DVM  
Diplomate, American College of Veterinary Ophthalmologists

Kristina R. Vygantas, DVM, Diplomate American College of Veterinary Ophthalmologists  
319 Perrineville Rd.  
Robbinsville, NJ 08691  
609.259.8300 (work)

Exam Date: October 21, 2016

Eurofins Study No: 43166  
PSL No. 160720-5R

40 male and 40 female SD rats were examined. The examination was performed under dim light conditions after pharmacologic mydriasis with 1% tropicamide ophthalmic solution. Both eyes of each animal were examined using slit lamp biomicroscopy and indirect ophthalmoscopy. All animals were all normal on ophthalmic exam, thus the test substance was not considered an ocular toxicant.

(b) (6)

Kristina R. Vygantas, DVM  
Diplomate, American College of Veterinary Ophthalmologists

## APPENDIX F: INDIVIDUAL ANIMAL IN-LIFE CLINICAL OBSERVATIONS<sup>1</sup>

### PRODUCT IDENTIFICATION

Soy Leghemoglobin Preparation

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<sup>1</sup> Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.



Individual Animal Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

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Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
1	m	7001	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7002	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7003	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7004	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7005	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7006	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7007	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7008	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7009	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7010	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

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Severity Codes: X = Present; S = Slight; M = Moderate; F = Superficial

Group 1 - 0 mg/kg/day      Group 2 - 512 mg/kg/day  
Group 3 - 1024 mg/kg/day    Group 4 - 1536 mg/kg/day

Individual Animal Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	2 0	2 1	2 2	2 3	2 4	2 5	2 6	2 7	2 8	2 9	3 0
1	m	7001	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7002	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7003	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7004	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7005	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7006	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7007	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7008	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7009	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7010	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.

Severity Codes: X = Present; S = Slight; M = Moderate; F = Superficial

Group 1 - 0 mg/kg/day      Group 2 - 512 mg/kg/day  
Group 3 - 1024 mg/kg/day    Group 4 - 1536 mg/kg/day

Individual Animal Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
2	m	7021	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7022	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7023	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7024	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7025	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7026	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7027	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7028	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7029	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7030	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Severity Codes: X = Present; S = Slight; M = Moderate; F = Superficial

Group 1 - 0 mg/kg/day      Group 2 - 512 mg/kg/day  
Group 3 - 1024 mg/kg/day    Group 4 - 1536 mg/kg/day

Individual Animal Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	2	2	2	2	2	2	2	2	2	2	3	
					0	1	2	3	4	5	6	7	8	9	0	
2	m	7021	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	.
		7022	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	.
		7023	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	.
		7024	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	.
		7025	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	.
		7026	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	.
		7027	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	.
		7028	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	.
		7029	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	.
		7030	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	.

Severity Codes: X = Present; S = Slight; M = Moderate; F = Superficial

Group 1 - 0 mg/kg/day      Group 2 - 512 mg/kg/day  
Group 3 - 1024 mg/kg/day      Group 4 - 1536 mg/kg/day

Individual Animal Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
3	m	7041	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7042	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7043	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7044	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7045	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7046	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7047	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7048	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7049	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7050	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Severity Codes: X = Present; S = Slight; M = Moderate; F = Superficial

Group 1 - 0 mg/kg/day      Group 2 - 512 mg/kg/day  
Group 3 - 1024 mg/kg/day      Group 4 - 1536 mg/kg/day

Individual Animal Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	2 0	2 1	2 2	2 3	2 4	2 5	2 6	2 7	2 8	2 9	3 0
3	m	7041	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7042	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7043	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7044	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7045	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7046	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7047	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7048	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7049	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7050	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.

Severity Codes: X = Present; S = Slight; M = Moderate; F = Superficial

Group 1 - 0 mg/kg/day      Group 2 - 512 mg/kg/day  
Group 3 - 1024 mg/kg/day    Group 4 - 1536 mg/kg/day

Individual Animal Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

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Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
4	m	7061	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
			Staining	Cage Pan	.	.	.	.	.	.	.	.	.	.	.	.	.	X	.	.	.	.	.	.
		7062	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7063	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7064	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7065	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
			Staining	Cage Pan	.	.	.	.	.	.	.	.	.	.	.	.	.	.	X	.	.	.	.	.
		7066	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
			Staining	Cage Pan	.	.	.	.	.	.	.	.	.	.	.	.	.	.	X	.	.	.	.	.
		7067	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
			Staining	Cage Pan	.	.	.	.	.	.	.	.	.	.	.	.	.	.	X	.	.	.	.	.
		7068	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
			Staining	Cage Pan	.	.	.	.	.	.	.	.	.	.	.	.	.	.	X	.	.	.	.	.
		7069	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
			Staining	Cage Pan	.	.	.	.	.	.	.	.	.	.	.	.	.	.	X	.	.	.	.	.
			Eschar	Head	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
		7070	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
			Staining	Cage Pan	.	.	.	.	.	.	.	.	.	.	.	.	.	.	X	.	.	.	.	.

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Severity Codes: X = Present; S = Slight; M = Moderate; F = Superficial

Group 1 - 0 mg/kg/day      Group 2 - 512 mg/kg/day  
Group 3 - 1024 mg/kg/day    Group 4 - 1536 mg/kg/day

Individual Animal Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	2 0	2 1	2 2	2 3	2 4	2 5	2 6	2 7	2 8	2 9	3 0
4	m	7061	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
			Staining	Cage Pan	.	.	.	.	.	.	.	.	.	.	.
		7062	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7063	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7064	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
		7065	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
			Staining	Cage Pan	.	.	.	.	.	.	.	.	.	.	.
		7066	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
			Staining	Cage Pan	.	.	.	.	.	.	.	.	.	.	.
		7067	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
			Staining	Cage Pan	.	.	.	.	.	.	.	.	.	.	.
		7068	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
			Staining	Cage Pan	.	.	.	.	.	.	.	.	.	.	.
		7069	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
			Staining	Cage Pan	.	.	.	.	.	.	.	.	.	.	.
			Eschar	Head	.	.	.	.	.	.	.	.	F	F	.
		7070	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	.
			Staining	Cage Pan	.	.	.	.	.	.	.	.	.	.	.

Severity Codes: X = Present; S = Slight; M = Moderate; F = Superficial

Group 1 - 0 mg/kg/day      Group 2 - 512 mg/kg/day  
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Individual Animal Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

-----  
Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	Day numbers relative to Start Date																				
					0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	
1	f	7011	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7012	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7013	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7014	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7015	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7016	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7017	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7018	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7019	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7020	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			

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Severity Codes: X = Present; S = Slight; M = Moderate; F = Superficial

Group 1 - 0 mg/kg/day      Group 2 - 512 mg/kg/day  
Group 3 - 1024 mg/kg/day      Group 4 - 1536 mg/kg/day

Individual Animal Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	2 0	2 1	2 2	2 3	2 4	2 5	2 6	2 7	2 8	2 9	3 0
1	f	7011	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7012	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7013	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7014	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7015	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7016	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7017	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7018	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7019	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7020	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X

Severity Codes: X = Present; S = Slight; M = Moderate; F = Superficial

Group 1 - 0 mg/kg/day      Group 2 - 512 mg/kg/day  
Group 3 - 1024 mg/kg/day      Group 4 - 1536 mg/kg/day

Individual Animal Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
2	f	7031	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7032	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7033	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7034	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7035	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
			Alopecia	Left Forelimb	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
			Alopecia	Right Forelimb	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
		7036	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7037	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7038	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7039	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		7040	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Severity Codes: X = Present; S = Slight; M = Moderate; F = Superficial

Group 1 - 0 mg/kg/day      Group 2 - 512 mg/kg/day  
Group 3 - 1024 mg/kg/day      Group 4 - 1536 mg/kg/day

Individual Animal Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	2 0	2 1	2 2	2 3	2 4	2 5	2 6	2 7	2 8	2 9	3 0
2	f	7031	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7032	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7033	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7034	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7035	No Abnormalities Detected		X	.	.	.	.	.	.	.	.	.	.
			Alopecia	Left Forelimb	.	S	S	S	S	S	S	S	M	M	M
			Alopecia	Right Forelimb	.	S	S	S	S	S	S	S	M	M	M
		7036	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7037	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7038	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7039	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7040	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X

Severity Codes: X = Present; S = Slight; M = Moderate; F = Superficial

Group 1 - 0 mg/kg/day      Group 2 - 512 mg/kg/day  
Group 3 - 1024 mg/kg/day      Group 4 - 1536 mg/kg/day

Individual Animal Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

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Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	Day numbers relative to Start Date																				
					0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	
3	f	7051	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7052	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7053	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7054	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7055	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7056	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7057	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7058	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7059	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
		7060	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			

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Severity Codes: X = Present; S = Slight; M = Moderate; F = Superficial

Group 1 - 0 mg/kg/day      Group 2 - 512 mg/kg/day  
Group 3 - 1024 mg/kg/day      Group 4 - 1536 mg/kg/day

Individual Animal Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	2 0	2 1	2 2	2 3	2 4	2 5	2 6	2 7	2 8	2 9	3 0
3	f	7051	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7052	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7053	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7054	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7055	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7056	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7057	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7058	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7059	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7060	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X

Severity Codes: X = Present; S = Slight; M = Moderate; F = Superficial

Group 1 - 0 mg/kg/day      Group 2 - 512 mg/kg/day  
Group 3 - 1024 mg/kg/day      Group 4 - 1536 mg/kg/day

Individual Animal Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	Day numbers relative to Start Date																											
					0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
4	f	7071	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
		7072	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
		7073	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
		7074	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
		7075	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
		7076	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
		7077	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
		7078	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
		7079	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
		7080	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	

Severity Codes: X = Present; S = Slight; M = Moderate; F = Superficial

Group 1 - 0 mg/kg/day      Group 2 - 512 mg/kg/day  
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Individual Animal Clinical Observations

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	2 0	2 1	2 2	2 3	2 4	2 5	2 6	2 7	2 8	2 9	3 0
4	f	7071	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7072	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7073	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7074	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7075	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7076	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7077	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7078	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7079	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X
		7080	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X

Severity Codes: X = Present; S = Slight; M = Moderate; F = Superficial

Group 1 - 0 mg/kg/day      Group 2 - 512 mg/kg/day  
 Group 3 - 1024 mg/kg/day      Group 4 - 1536 mg/kg/day



**APPENDIX G: DETAILED CLINICAL OBSERVATIONS ASSESSMENT METHODS  
SCORING KEY**

**PRODUCT IDENTIFICATION**

Soy Leghemoglobin Preparation

## APPENDIX G: DETAILED CLINICAL OBSERVATIONS ASSESSMENT METHODS SCORING KEY

<b>Removal from Cage and Open Field Observations</b>	
<u>Activity/Arousal</u>	0. Alternating behaviors - animal goes through normal repertoire of behaviors during observation period. These consist of exploring, sniffing, grooming, rearing, etc. 1. Inactive/Alert - animal sits in one place during the observation period but appears to be aware of its surroundings. It may go through its normal repertoire of activities but the majority of the observation period is spent not moving. 2. Hypoactive/Not alert - animal sits in one place during the observation period. Animal appears to be unaware of its surroundings or in a stupor. 3. Hyperactive/Hyperalert - animal appears excited. Animal may dart and freeze during the observation period or animal may sit in one place and jump at any sound or movement.
<u>Biting</u>	0. None 1. Biting cage 2. Self-mutilation
<u>Circling</u>	0. Absent 1. Present
<u>Convulsions</u>	0. None 1. Clonic – alternating periods of contraction and relaxation of muscles 2. Tonic – prolonged period of muscle contractions
<u>Defecation</u>	0. None/Normal 1. Soft (partially formed) 2. Diarrhea (watery feces)
<u>Ease of Removal/Handling</u>	0. Slight/moderate resistance - animal is easy to handle, may squirm or vocalize occasionally. 1. No resistance - animal is limp/flaccid when being handled. 2. High resistance/aggressive - animal is difficult to handle, and/or squirms continuously, and/or tries to bite handler. 3. Aggressive - biting or lunging behavior specifically directed at handler.
<u>Emaciation</u>	0. Absent 1. Present (confirmed using body weights)
<u>Eyes</u>	0. Normal 1. Exophthalmos - abnormal protrusion of eyeball 2. Endophthalmus – sunken eyeball 3. Eye damaged – mechanical damage (e.g. orbital bleeding, etc.)
<u>Fur/Skin Appearance</u>	0. Normal 1. Unkempt - coat rough or ungroomed, may be slightly stained 2. Urine stained/wetness (Ano-genital staining) 3. Hair loss
<u>Gait</u>	0. Normal 1. Abnormal – limbs exaggerated/splayed, hind limbs and/or forelimbs show exaggerated placement or movement 2. Non weight bearing (Limping)
<u>Lacrimation</u>	0. Absent 1. Present - lacrimation noticeable. 2. Excessive - animal has excessive amount of tearing. Note: Descriptors (i.e. color of ocular discharge will be noted on daily observation sheet).
<u>Locomotion</u>	0. Normal 1. Somewhat impaired 2. Totally impaired

**APPENDIX G (cont.): DETAILED CLINICAL OBSERVATIONS ASSESSMENT METHODS  
SCORING KEY**

<u>Mucous Membranes</u>	0. Normal 1. Present – mucous noticeable 2. Excessive – animal has an excessive amount of mucous present
<u>Muscle Tone</u>	0. Normal - muscles are resilient and firm and the hind legs go through their full range of motion. 1. Increased - muscles are rigid, hind limbs will not go through their full range of motion. 2. Decreased - muscles are flaccid, hind limbs have little or no resistance to movement
<u>Palpebral Closure</u>	0. Eyes wide open 1. Eyes halfway shut 2. Eyes completely shut
<u>Piloerection</u>	0. Absent 1. Present
<u>Posture</u>	0. Normal (awake) – alert, sitting, standing, or rearing 1. Normal (sleeping) – curled up, usually with head down 2. Hunched – abnormal posture 3. Flattened (prone) – limbs spread out lying flat or on one side
<u>Respiratory Pattern</u>	0. Normal 1. Slow 2. Rapid 3. Rales (Moist or Dry) 4. Gasping 5. Labored - Dyspnea
<u>Salivation</u>	0. None 1. Present - salivation is noticeable around the edge of the mouth 2. Excessive - salivation extends to the fur around the jaw
<u>Tremors</u>	0. None 1. Slight – localized to one area, or a twitch/spasm of a localized area 2. Severe – more than one area or involving whole body 3. Fasciculation – wave-like ripples of a muscle or group of muscles
<u>Unusual Behaviors</u>	0. Absent 1. Present – Be specific in describing all unusual behaviors on data sheet.
<u>Urination</u>	0. None/Normal 1. Excessive
<u>Vocalization, removal from cage</u>	0. Absent 1. Present - animal vocalizes unprovoked or continuously vocalizes when being handled.
<u>Vocalizations, open field observations</u>	0. Absent 1. Present
<u>Writhing</u>	0. Absent 1. Present
<b>Manipulative Tests</b>	
<u>Pupillary reflex</u>	0. Normal 1. Slow or absent- pupil reaction is slow or absent.

## APPENDIX H: INDIVIDUAL ANIMAL DETAILED CLINICAL OBSERVATIONS<sup>1</sup>

### PRODUCT IDENTIFICATION

Soy Leghemoglobin Preparation

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<sup>1</sup> Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male	Day(s) Relative to Start Date	Det/Clin/Obs (Removal from Cage)													
		Handling Reactivity	Handling Reactivity	Handling Reactivity	Handling Reactivity	Handling Reactivity	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Palpebral Closure	Palpebral Closure
0		7	14	21	28	0	7	14	21	28	0	7	14	21	
7001		0	0	0	0	0	0	0	0	0	0	0	0	0	
7002		0	0	0	0	0	0	0	0	0	0	0	0	0	
7003		0	0	0	0	0	0	0	0	0	0	0	0	0	
7004		0	0	0	0	0	0	0	0	0	0	0	0	0	
7005		0	0	0	0	0	0	0	0	0	0	0	0	0	
7006		0	0	0	0	0	0	0	0	0	0	0	0	0	
7007		0	0	0	0	0	0	0	0	0	0	0	0	0	
7008		0	0	0	0	0	0	0	0	0	0	0	0	0	
7009		0	0	0	0	0	0	0	0	0	0	0	0	0	
7010		0	0	0	0	0	0	0	0	0	0	0	0	0	

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male	Day(s) Relative to Start Date	DetClmObs (Removal from Cage)													
		Palpebral Closure	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Eye	Eye	Eye	Eye	Eye	Mucous Membranes	Mucous Membranes
0	28	0	0	7	14	21	28	0	7	14	21	28	0	7	14
7001	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7002	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7003	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7004	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7005	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7006	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7007	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7008	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7009	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7010	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Insg/day Group 1	Sex: Male	Day(s) Relative to Start Date	Decline/Res (Removal from Cage)																							
			Mucous Membranes		Salivation		Salivation		Salivation		Salivation		Salivation		Salivation											
			21	28	0	7	14	21	28	0	7	14	21	28	0	7										
7001			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
7002			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
7003			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7004			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7005			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7006			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7007			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7008			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7009			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7010			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
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Imp/sg/day Group 1	14		21		28		7		14		21		28		7		14		21		28		Respiratory Pattern
	Tiliberaction	Piloveraction	Tiliberaction	Piloveraction	Tiliberaction	Piloveraction	Tiliberaction	Piloveraction	Tiliberaction	Piloveraction	Tiliberaction	Piloveraction	Tiliberaction	Piloveraction	Tiliberaction	Piloveraction	Tiliberaction	Piloveraction	Tiliberaction	Piloveraction	Tiliberaction	Piloveraction	
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7001	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7002	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7003	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7004	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7005	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7006	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7007	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7008	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7009	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7010	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0



Individual Animal Detailed Clinical Observations  
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Sex: Male Day(s) Relative to Start Date

Imp/Sp/day Group 1	Respiratory Pattern			Respiratory Pattern			Respiratory Pattern			Respiratory Pattern			Respiratory Pattern			Respiratory Pattern			Respiratory Pattern					
	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28
7001	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7002	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7003	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7004	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7005	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7006	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7007	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7008	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7009	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7010	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
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Sex: Male Age/Day Group 1	Day(s) Relative to Start Date																							
	0		7		14		21		28		7		14		21		28		7		14		21	
	Convolutions	Convolutions	Convolutions	Convolutions	Convolutions	Convolutions	Convolutions	Convolutions	Convolutions	Convolutions	Tremors	Tremors	Tremors	Tremors	Tremors	Tremors	Tremors	Tremors	Posture	Posture	Posture	Posture	Posture	Posture
7001	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7002	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7003	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7004	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7005	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7006	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7007	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7008	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7009	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7010	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
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Sex: Male	Day(s) Relative to Start Date	Det/Clm/Chr (Open Field Obs)															
		Posture		Gait		Gait		Gait		Locomotion		Locomotion		Locomotion		Defecation	
		Posture	Gait	Posture	Gait	Posture	Gait	Posture	Gait	Posture	Gait	Posture	Gait	Posture	Gait	Posture	Gait
	28	0	0	7	1.4	21	28	0	0	7	1.4	21	28	0	0	7	1.4
7001	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7002	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7003	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7004	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7005	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7006	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7007	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7008	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7009	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7010	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
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Inp/sg/day Group 1	Sex: Male Day(s) Relative to Start Date																							
	21		28		7		14		21		28		7		14		21		28		7			
	Defecation	Defecation	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Vocalization (OF)	Vocalization (OF)	
7001	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7002	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7003	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7004	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7005	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7006	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7007	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7008	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7009	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7010	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
 PSL Study Number 43166  
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Sex: Male Days Relative to Start Date

ID Imp/Agg/day Group 1	Days Relative to Start Date		
	1-4	21	28
7001	0	0	0
7002	0	0	0
7003	0	0	0
7004	0	0	0
7005	0	0	0
7006	0	0	0
7007	0	0	0
7008	0	0	0
7009	0	0	0
7010	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male	Day(s) Relative to Start Date	DetChinObs (Removal from Cage)																			
		Handling Reactivity	Handling Reactivity	Handling Reactivity	Handling Reactivity	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)										
512																					
mg/kg/day Group 2																					
	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0
7021	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7022	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7023	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7024	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7025	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7026	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7027	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7028	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7029	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7030	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
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Site	Sex: Male	Day (g) Relative to Start Date	De/Clin Obs (Removal from Cage)													
			Palpebral Closure	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Eye	Eye	Eye	Eye	Eye	Eye	Mucous Membranes	Mucous Membranes
512			28	0	7	14	21	28	0	7	14	21	28	0	7	14
7021			0	0	0	0	0	0	0	0	0	0	0	0	0	0
7022			0	0	0	0	0	0	0	0	0	0	0	0	0	0
7023			0	0	0	0	0	0	0	0	0	0	0	0	0	0
7024			0	0	0	0	0	0	0	0	0	0	0	0	0	0
7025			0	0	0	0	0	0	0	0	0	0	0	0	0	0
7026			0	0	0	0	0	0	0	0	0	0	0	0	0	0
7027			0	0	0	0	0	0	0	0	0	0	0	0	0	0
7028			0	0	0	0	0	0	0	0	0	0	0	0	0	0
7029			0	0	0	0	0	0	0	0	0	0	0	0	0	0
7030			0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
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SI2 mg/kg/day Group 2	Sex: Male	Day(s) Relative to Start Date	Mucous Membranes			Salivations			Detritus (Removal From Cage)			Ennuciation			Piloerection		
			21	28	0	7	14	21	28	0	7	14	21	28	0	7	
7021			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7022			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7023			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7024			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7025			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7026			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7027			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7028			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7029			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7030			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0



Individual Animal Detailed Clinical Observations  
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A 28-Day Dietary Study in Rats

S12 Imp/Sp/day Group 2	Sex: Male Day(s) Relative to Start Date																					
	14		21		28		7		14		21		28		0							
Piloerection		Piloerection		Piloerection		Fur/Skin		Fur/Skin		Fur/Skin		Fur/Skin		Muscle Tones		Muscle Tones		Muscle Tones		Respiratory Pattern		
7021	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7022	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7023	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7024	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7025	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7026	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7027	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7028	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7029	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7030	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
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SI2 Imp/kg/day Group 2	Sex: Male	Day(s) Relative to Start Date	Dec/ClincObs (Removal from Cage)						Dec/ClincObs (Open Field/Obs)									
			Respiratory Pattern		Respiratory Pattern		Pupillary Reflex		Respiratory Pattern		Respiratory Pattern		Activity/Arousal		Activity/Arousal			
			7	14	21	28	7	14	21	28	7	14	21	28	7	14	21	28
7021			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7022			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7023			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7024			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7025			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7026			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7027			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7028			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7029			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7030			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
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S12 mp/kg/day Group 2	Day(s) Relative to Start Date														
	0	7	14	21	28	Det/In/Obs (Open Field Obs)									
	Convsions	Convsions	Convsions	Convsions	Convsions	Tremors	Tremors	Tremors	Tremors	Tremors	Tremors	Posture	Posture	Posture	Posture
7021	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7022	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7023	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7024	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7025	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7026	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7027	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7028	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7029	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7030	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
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Site/Inj/kg/day Group	Sex: Male	Day(s) Relative to Start Date	DeClnObs (Open Field Obs)																
			Posture		Gait		Gait		Gait		Gait		Locomotion		Locomotion		Defecation		
			28	0	7	0	14	0	21	0	28	0	7	14	21	28	0	7	14
7021			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7022			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7023			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7024			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7025			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7026			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7027			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7028			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7029			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7030			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
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Imp/Study Group 2	Sex: Male							Day(s) Relative to Start Date							DetClimObs (Open Field Obs)										
	21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	7	
	Defecation	Defecation	Urination	Urination	Urination	Urination	Urination	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Vocalization (Of)	Vocalization (Of)
7021	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7022	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7023	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7024	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7025	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7026	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7027	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7028	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7029	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7030	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Delay Study in Rats

Sex: Male Day(s) Relative to Start Date

SID Inp/Ky/day Group 2	Day(s) Relative to Start Date		
	14	21	28
7021	0	0	0
7022	0	0	0
7023	0	0	0
7024	0	0	0
7025	0	0	0
7026	0	0	0
7027	0	0	0
7028	0	0	0
7029	0	0	0
7030	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

T024 mg/kg/day Group 3	Sex: Male Day(s) Relative to Start Date													
	Handling Reactivity							Det/Clin Obs (Removal from Cage)						
	7	14	21	28	0	7	14	21	28	0	7	14	21	28
	Handling Reactivity	Handling Reactivity	Handling Reactivity	Handling Reactivity	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)
7041	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7042	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7043	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7044	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7045	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7046	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7047	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7048	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7049	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7050	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Day(s) Relative to Start Date

1024 Insgp/day Group 3	DetClnObs (Removal from Cage)														
	Palpebral Closure	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Eye	Eye	Eye	Eye	Eye	Eye	Mucous Membranes	Mucous Membranes
	28	0	7	14	21	28	0	7	14	21	28	0	7	14	
7041	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7042	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7043	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7044	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7045	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7046	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7047	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7048	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7049	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7050	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0





Individual Animal Detailed Clinical Observations

PSL Study Number 43168  
A 28-Day Dietary Study in Rats

Sex: Male Day(s) Relative to Start Date

1024 mg/kg/day Group 3	DetClinObs (Removal from Cage)														
	Piloerection	Piloerection	Piloerection	Fur/Skin	Fur/Skin	Fur/Skin	Fur/Skin	Fur/Skin	Muscle Tone	Muscle Tone	Muscle Tone	Muscle Tone	Muscle Tone	Respiratory Pattern	
	14	21	28	0	7	14	21	28	0	7	14	21	28	0	
7041	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7042	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7043	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7044	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7045	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7046	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7047	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7048	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7049	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7050	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male		Day(s) Relative to Start Date												
1024 mg/kg/day Group 3	DetClinObs (Removal from Cage)									DetClinObs (Open Field Obs)				
	Respiratory Pattern	Respiratory Pattern	Respiratory Pattern	Respiratory Pattern	Pupillary Reflex	Pupillary Reflex	Pupillary Reflex	Pupillary Reflex	Pupillary Reflex	Activity/ Arousal	Activity/ Arousal	Activity/ Arousal	Activity/ Arousal	Activity/ Arousal
	7	14	21	28	0	7	14	21	28	0	7	14	21	28
7041	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7042	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7043	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7044	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7045	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7046	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7047	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7048	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7049	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7050	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Male Day(s) Relative to Start Date

1024 mg/kg/day Group 3	DetClinObs (Open Field Obs)														
	Convulsions	Convulsions	Convulsions	Convulsions	Convulsions	Tremors	Tremors	Tremors	Tremors	Tremors	Posture	Posture	Posture	Posture	
	0	7	14	21	28	0	7	14	21	28	0	7	14	21	
7041	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7042	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7043	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7044	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7045	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7046	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7047	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7048	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7049	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7050	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
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Sex: Male	Day(s) Relative to Start Date	Det/In/Obs (Open Field Obs)													
		Posture	Gait	Gait	Gait	Gait	Gait	Locomotion	Locomotion	Locomotion	Locomotion	Locomotion	Locomotion	Defecation	Defecation
		28	0	7	14	21	28	0	7	14	21	28	0	7	14
7041		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7042		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7043		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7044		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7045		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7046		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7047		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7048		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7049		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7050		0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
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A 28-Day Dietary Study in Rats

1024 mg/kg/day Group 3	Sex: Male	Day(s) Relative to Start Date	DetChinObs (Open Field Obs)																			
			Defecation	Defecation	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Unusual Behaviors	Unusual Behaviors (OF)	Vocalization (OF)	Vocalization (OF)				
			21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	7	
7041			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7042			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7043			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7044			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7045			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7046			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7047			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7048			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7049			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7050			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
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A 28-Day Decay Study in Rats

Sex: Male Day(s) Relative to Start Date

LO24 Insg/Day/ Group 3	Dec/In/Obv (Open Field Obs)	
	Vocalization (OF)	Vocalization (OF)
	14	21
		28
7041	0	0
7042	0	0
7043	0	0
7044	0	0
7045	0	0
7046	0	0
7047	0	0
7048	0	0
7049	0	0
7050	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

1536 Ings/Spdy Group 1	Sex: Male Day(s) Relative to Start Date														
	Handling Reactivity	Handling Reactivity	Handling Reactivity	Handling Reactivity	Handling Reactivity	Handling Reactivity	DetClnObs (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Pulpobral Closure	Pulpobral Closure
0	7	14	21	28	0	7	14	21	28	0	7	14	21	0	0
7061	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7062	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7063	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7064	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7065	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7066	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7067	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7068	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7069	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7070	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0



Individual Animal Detailed Clinical Observations  
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Imp/Sp/Day Group 1	Sex: Male	Day(s) Relative to Start Date	Det/Clnc/Chr (Removal from Cage)																	
			Palpebral Closure	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Eye	Eye	Eye	Eye	Eye	Mucous Membranes	Mucous Membranes	Mucous Membranes	Mucous Membranes	
			28	0	7	14	21	28	0	7	14	21	28	0	7	14	28	0	7	14
7061			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7062			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7063			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7064			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7065			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7066			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7067			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7068			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7069			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7070			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
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Sex: Male	Day(s) Relative to Start Date	DesClincObs (Removal from Cage)																	
		Mucous Membranes		Salivation		Salivation		Salivation		Salivation		Emaciation		Emaciation		Piloerection			
		21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	
1536	mp/kg/day																		
Group 4																			
7061		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7062		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7063		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7064		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7065		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7066		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7067		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7068		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7069		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7070		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male	Day(s) Relative to Start Date	Det/Clin Obs (Removal From Cage)													
		Phloerecton	Phloerecton	Phloerecton	Pur/Skin	Pur/Skin	Pur/Skin	Pur/Skin	Pur/Skin	Pur/Skin	Pur/Skin	Pur/Skin	Pur/Skin	Pur/Skin	Pur/Skin
	1-4	21	28	0	7	1-4	21	28	0	7	1-4	21	28	0	0
7061	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7062	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7063	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7064	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7065	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7066	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7067	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7068	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7069	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7070	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male	Day(s) Relative to Start Date	Respiratory Pattern			Respiratory Pattern			Respiratory Pattern			Respiratory Pattern			Pupillary Reflex			Pupillary Reflex			Pupillary Reflex			Pupillary Reflex			Activity/Arousal			Activity/Arousal			Activity/Arousal					
		7	14	21	28	7	14	21	28	7	14	21	28	7	14	21	28	7	14	21	28	7	14	21	28	7	14	21	28	7	14	21	28				
1536																																					
ing/kg/day Group 1																																					
7061		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
7062		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
7063		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7064		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7065		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7066		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7067		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7068		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7069		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7070		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male	Day(s) Relative to Start Date	Det/Clin/Obs (Open Field Obs)													
		Convsions	Convsions	Convsions	Convsions	Tremors	Tremors	Tremors	Tremors	Tremors	Tremors	Posture	Posture	Posture	Posture
1536	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7061	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7062	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7063	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7064	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7065	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7066	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7067	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7068	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7069	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7070	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Insgp/day Group 1	Day(s) Relative to Start Date		Day(s) Relative to Start Date		Day(s) Relative to Start Date		Day(s) Relative to Start Date		Day(s) Relative to Start Date		Day(s) Relative to Start Date		Day(s) Relative to Start Date		Day(s) Relative to Start Date		Day(s) Relative to Start Date		
	Posture	Gait	Gait	Gait	Gait	Gait	Gait	Gait	Gait	Gait	Gait	Gait	Gait	Gait	Gait	Gait	Gait	Gait	
																			Locomotion
7061	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7062	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7063	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7064	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7065	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7066	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7067	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7068	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7069	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7070	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male	Day(s) Relative to Start Date	Det/ClinObs (Open Field Obs)														
		Defecation	Defecation	Urination	Urination	Urination	Urination	Urination	Urination	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Vocalization (OF)	Vocalization (OF)
	21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	28	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7061	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7062	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7063	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7064	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7065	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7066	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7067	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7068	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7069	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7070	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Day(s) Relative to Start Date

USC Imp/Day Group 1	DetChinObs (Open Field Obs) Vocalization (OF)		Vocalization/Vocalization (OF)	
	14	21	28	28
7061	0	0	0	0
7062	0	0	0	0
7063	0	0	0	0
7064	0	0	0	0
7065	0	0	0	0
7066	0	0	0	0
7067	0	0	0	0
7068	0	0	0	0
7069	0	0	0	0
7070	0	0	0	0



Individual Animal Detailed Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

0 mg/kg/day Group 1	DetClinObs (Removal from Cage)													
	Handling Reactivity	Handling Reactivity	Handling Reactivity	Handling Reactivity	Handling Reactivity	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Palpebral Closure	Palpebral Closure	Palpebral Closure	Palpebral Closure
	0	7	14	21	28	0	7	14	21	28	0	7	14	21
7011	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7012	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7013	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7014	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7015	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7016	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7017	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7018	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7019	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7020	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female	Day(s) Relative to Start Date	DeClincObs (Removal from Cage)															
		Palpebral Closure	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Eye	Eye	Eye	Eye	Eye	Mucous Membranes	Mucous Membranes	Mucous Membranes
0	mp/kg/day Group 1	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28
	7011	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7012	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7013	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7014	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7015	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7016	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7017	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7019	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

θ img&id's Group 1	Sex: Female		Day(s) Relative to Start Date		Det/ClinObs (Removal from Cage)																			
	Mucous Membranes		Salivation		Salivation		Salivation		Salivation		Salivation		Salivation		Salivation		Salivation		Salivation		Salivation		Salivation	
	21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	7
7011	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7012	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7013	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7014	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7015	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7016	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7017	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7019	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Delay Study in Rats

Imp/Day/Group	Sex: Female	Day(s) Relative to Start Date	Det/Clin Obs (Removal from Cage)														
			Piloerection		Piloerection		Fur/Skin		Fur/Skin		Muscle Tone		Muscle Tone		Muscle Tone		Respiratory Pattern
			14	21	28	0	7	14	21	28	0	7	14	21	28		
7011			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7012			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7013			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7014			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7015			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7016			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7017			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7018			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7019			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7020			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

0 mg/kg/day Group 1	DetClnObs (Removal from Cage)									DetClnObs (Open Field Obs)				
	Respiratory Pattern	Respiratory Pattern	Respiratory Pattern	Respiratory Pattern	Pupillary Reflex	Pupillary Reflex	Pupillary Reflex	Pupillary Reflex	Pupillary Reflex	Activity/ Arousal	Activity/ Arousal	Activity/ Arousal	Activity/ Arousal	Activity/ Arousal
	7	14	21	28	0	7	14	21	28	0	7	14	21	28
7011	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7012	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7013	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7014	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7015	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7016	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7017	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7018	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7019	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7020	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Delay Study in Rats

Imp/Ag/day Group 1	Sex: Female Day(s) Relative to Start Date														
	DesClincObs (Open Field Obs)							DesClincObs (Open Field Obs)							
	Convolutions	Convolutions	Convolutions	Convolutions	Convolutions	Convolutions	Convolutions	Tremors	Tremors	Tremors	Tremors	Tremors	Tremors	Posture	Posture
	0	7	14	21	28	0	7	14	21	28	0	7	14	21	
7011	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7012	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7013	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7014	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7015	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7016	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7017	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7019	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Days(s) Relative to Start Date

Imp/Study Group 1	Posture	Det/Clin/Obs (Open Field Obs)												
		Gait	Gait	Gait	Gait	Locomotion	Locomotion	Defecation						
	28	0	7	14	21	28	0	7	14	21	28	0	7	14
7011	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7012	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7013	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7014	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7015	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7016	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7017	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7018	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7019	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7020	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Imp/Sp/Day Group 1	Sex: Female Day(s) Relative to Start Date																						
	21		28		7		14		21		28		7		14		21		28		7		
	Defecation	Defecation	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Vocalization (OF)	Vocalization (OF)
7011	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7012	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7013	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7014	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7015	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7016	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7017	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7019	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7020	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0



Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Days Relative to Start Date

Inp/Day/Day Group 1	Days Relative to Start Date		
	1-4	21	28
7011	0	0	0
7012	0	0	0
7013	0	0	0
7014	0	0	0
7015	0	0	0
7016	0	0	0
7017	0	0	0
7018	0	0	0
7019	0	0	0
7020	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female	Day(s) Relative to Start Date	Detritus (Removal from Cage)																		
		Handling Reactivity	Handling Reactivity	Handling Reactivity	Handling Reactivity	Handling Reactivity	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Palpebral Closure	Palpebral Closure	Palpebral Closure	Palpebral Closure				
	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	
7031	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7032	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7033	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7034	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7035	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7036	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7037	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7038	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7039	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7040	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female	Day(s) Relative to Start Date	Det/Clin/Obs (Removal From Cage)													
		Palpebral Closure	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Eye	Eye	Eye	Eye	Eye	Eye	Mucous Membranes
	28	0	0	7	14	21	28	0	7	14	21	28	0	7	14
7031		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7032		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7033		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7034		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7035		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7036		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7037		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7038		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7039		0	0	0	0	0	0	0	0	0	0	0	0	0	0
7040		0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female	Day(s) Relative to Start Date	Detritus (Removal from Cage)																	
		Mucous Membranes		Salivation		Salivation		Salivation		Salivation		Emaciation		Emaciation		Emaciation			
		21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	
512	Imp/Ag/day Group 2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7031		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7032		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7033		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7034		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7035		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7036		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7037		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7038		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7039		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7040		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

S12 mg/kg/day Group 2	DetClinObs (Removal from Cage)													
	Piloerection	Piloerection	Piloerection	Fur/Skin	Fur/Skin	Fur/Skin	Fur/Skin	Fur/Skin	Muscle Tone	Muscle Tone	Muscle Tone	Muscle Tone	Muscle Tone	Respiratory Pattern
	14	21	28	0	7	14	21	28	0	7	14	21	28	0
7031	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7032	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7033	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7034	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7035	0	0	0	0	0	0	3	3	0	0	0	0	0	0
7036	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7037	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7038	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7039	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7040	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female		Day(s) Relative to Start Date													
512 mg/kg/day Group 2	DetClinObs (Removal from Cage)									DetClinObs (Open Field Obs)					
	Respiratory Pattern	Respiratory Pattern	Respiratory Pattern	Respiratory Pattern	Pupillary Reflex	Pupillary Reflex	Pupillary Reflex	Pupillary Reflex	Pupillary Reflex	Activity/ Arousal	Activity/ Arousal	Activity/ Arousal	Activity/ Arousal	Activity/ Arousal	
	7	14	21	28	0	7	14	21	28	0	7	14	21	28	
7031	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
7032	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
7033	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
7034	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
7035	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
7036	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
7037	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
7038	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
7039	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
7040	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

512 mg/kg/day Group 2	DetClnObs (Open Field Obs)													
	Convsions	Convsions	Convsions	Convsions	Convsions	Convsions	Convsions	Convsions	Convsions	Convsions	Convsions	Convsions	Posture	Posture
	0	7	14	21	28	0	7	14	21	28	0	7	14	21
7031	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7032	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7033	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7034	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7035	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7036	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7037	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7038	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7039	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7040	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Diets Study in Rats

Sex: Female Day(s) Relative to Start Date

InpKs/day Group 2	28		7		14		21		28		7		14		21		28		7		14		
	Posture	Gait	Posture	Gait	Posture	Gait	Posture	Gait	Posture	Gait	Posture	Gait	Posture	Gait	Posture	Gait	Posture	Gait	Posture	Gait	Posture	Gait	
512																							
7031	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7032	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7033	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7034	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7035	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7036	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7037	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7038	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7039	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7040	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0



Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Days Relative to Start Date

Site Inns/day Group 2	Det/ClmObs (Open Field Obs)															
	Defecation	Defecation	Urination	Urination	Urination	Urination	Urination	Urination	Urination	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Vocalization (OF)	Vocalization (OF)
	21	28	0	7	14	21	28	0	7	14	21	28	0	7		
7031	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7032	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7033	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7034	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7035	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7036	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7037	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7038	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7039	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7040	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
 PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Female	Day(s) Relative to Start Date	De(Cl)in(Ch) (Open Field Obs)		
		Vocalization (OF)	Vocalization (OF)	Vocalization (OF)
512		14	21	28
mg/kg/day Group 2				
7031		0	0	0
7032		0	0	0
7033		0	0	0
7034		0	0	0
7035		0	0	0
7036		0	0	0
7037		0	0	0
7038		0	0	0
7039		0	0	0
7040		0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

1024 Insg/day Group 3	Det/Clin Obs (Removal from Cage)													
	0	7	14	21	28	0	7	14	21	28	0	7	14	21
	Handling Reactivity	Handling Reactivity	Handling Reactivity	Handling Reactivity	Handling Reactivity	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)
7051	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7052	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7053	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7054	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7055	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7056	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7057	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7058	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7059	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7060	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

1024 Inj/Sp/Day Group 3	Palpebral Closure		Lacrimation		Lacrimation		Lacrimation		Lacrimation		Lacrimation		Eye		Eye		Eye		Mucous Membranes		Mucous Membranes	
	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	28	0	7
7051	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7052	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7053	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7054	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7055	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7056	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7057	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7058	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7059	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7060	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

1024 mg/kg/day Group 3	DetClinObs (Removal from Cage)													
	Mucous Membranes	Mucous Membranes	Salivation	Salivation	Salivation	Salivation	Salivation	Emaciation	Emaciation	Emaciation	Emaciation	Emaciation	Piloerection	Piloerection
	21	28	0	7	14	21	28	0	7	14	21	28	0	7
7051	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7052	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7053	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7054	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7055	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7056	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7057	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7058	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7059	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7060	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female	Day(s) Relative to Start Date	Det/Clin Obs (Removal from Cage)																			
		Piloerection		Fur/Skin		Fur/Skin		Fur/Skin		Muscle Tone		Muscle Tone		Muscle Tone		Respiratory Pattern					
11024 mg/kg/day Group 3		14	21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	
7051	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7052	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7053	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7054	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7055	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7056	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7057	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7058	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7059	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7060	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

1024 Inpkg/day Group 3	DetClimObs (Respiratory from Cage)						DetClimObs (Open Field Obs)													
	Respiratory Pattern		Respiratory Pattern		Respiratory Pattern		Pupillary Reflex		Pupillary Reflex		Pupillary Reflex		Activity/Arousal		Activity/Arousal		Activity/Arousal			
	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	
7051	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7052	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7053	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7054	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7055	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7056	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7057	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7058	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7059	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7060	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

[024 Ings/Day Group 3	DetClnObs (Open Field Obs)																		
	Convs	Convs	Convs	Convs	Convs	Convs	Convs	Convs	Convs	Convs	Convs	Convs	Convs	Convs	Convs				
	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21
7051	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7052	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7053	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7054	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7055	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7056	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7057	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7058	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7059	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7060	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0



Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

Time/Day Group 3	Posture		Gait		Gait		Gait		Gait		Gait		Gait		Gait		Gait		Gait		Gait		Gait		Gait		Gait					
	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	7	14			
7051	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
7052	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
7053	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7054	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7055	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7056	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7057	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7058	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7059	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7060	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

1024 mg/kg/day Group 3	DetClinObs (Open Field Obs)													
	Defecation	Defecation	Urination	Urination	Urination	Urination	Urination	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Vocalization (OF)	Vocalization (OF)
	21	28	0	7	14	21	28	0	7	14	21	28	0	7
7051	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7052	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7053	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7054	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7055	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7056	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7057	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7058	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7059	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7060	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female 1024 img/Asp/day Group 3	Day(s) Relative to Start Date			
	1-4	21	28	
	DetClipObs (OF)	DetClipObs (OF)	DetClipObs (OF)	DetClipObs (OF)
7051	0	0	0	0
7052	0	0	0	0
7053	0	0	0	0
7054	0	0	0	0
7055	0	0	0	0
7056	0	0	0	0
7057	0	0	0	0
7058	0	0	0	0
7059	0	0	0	0
7060	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

1536 mg/kg/day Group 4	Sex: Female		Day(s) Relative to Start Date		DetClimObs (Removal from Cage)															
	Handling Reactivity	Handling Reactivity	Handling Reactivity	Handling Reactivity	Handling Reactivity	Handling Reactivity	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Vocalization (RC)	Palpebral Closure	Palpebral Closure	Palpebral Closure	Palpebral Closure			
	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	
7071	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7072	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7073	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7074	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7075	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7076	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7077	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7078	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7079	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7080	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

US36 Site/Day Group 1	Det/ClinObs (Removal from Cage)														
	Palpebral Closure	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Lacrimation	Eye	Eye	Eye	Eye	Eye	Eye	Eye	Mucous Membranes	Mucous Membranes
	28	0	7	14	21	28	0	7	14	21	28	0	7	14	
7071	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7072	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7073	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7074	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7075	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7076	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7077	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7078	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7079	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7080	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Delay Study in Rats

Sex: Female Insg/kg/day Group 1	Day(s) Relative to Start Date		DetClnObs (Removal from Cage)																	
	Mucous Membranes		Salivation		Salivation		Salivation		Salivation		Emaciation		Emaciation		Emaciation		Piloerection			
	21	28	0	7	14	21	28	0	7	14	21	28	0	7	14	21	28	0	7	
7071	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7072	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7073	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7074	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7075	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7076	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7077	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7078	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7079	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7080	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female		Day(s) Relative to Start Date													
1536 mg/kg/day Group 1	DetClinObs (Removal from Cage)														
	Piloerection	Piloerection	Piloerection	Fur/Skin	Fur/Skin	Fur/Skin	Fur/Skin	Fur/Skin	Fur/Skin	Muscle Tone	Muscle Tone	Muscle Tone	Muscle Tone	Muscle Tone	Respiratory Pattern
	14	21	28	0	7	14	21	28	0	7	14	21	28	0	
7071	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7072	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7073	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7074	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7075	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7076	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7077	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7078	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7079	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7080	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female	Day(s) Relative to Start Date	DetClinObs (Removal from Cage)			DetClinObs (Open Field Obs)			
		Respiratory Pattern	Respiratory Pattern	Pupillary Reflex	Activity/Arousal	Activity/Arousal	Activity/Arousal	
1536	7	14	21	28	7	14	21	28
7071	0	0	0	0	0	0	0	0
7072	0	0	0	0	0	0	0	0
7073	0	0	0	0	0	0	0	0
7074	0	0	0	0	0	0	0	0
7075	0	0	0	0	0	0	0	0
7076	0	0	0	0	0	0	0	0
7077	0	0	0	0	0	0	0	0
7078	0	0	0	0	0	0	0	0
7079	0	0	0	0	0	0	0	0
7080	0	0	0	0	0	0	0	0



Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Pats

Sex: Female Days Relative to Start Date

ImpAs/Day Group 4	DetClinObs (Open Field Obs)													
	Convsions	Convsions	Convsions	Convsions	Convsions	Tremors	Tremors	Tremors	Tremors	Tremors	Posture	Posture	Posture	Posture
	0	7	14	21	28	0	7	14	21	28	0	7	14	21
7071	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7072	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7073	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7074	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7075	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7076	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7077	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7078	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7079	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7080	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

I336 Inp/No/day Group 1	Sex: Female		Day(s) Relative to Start Date		Day(s) Relative to Start Date		Day(s) Relative to Start Date		Day(s) Relative to Start Date		Day(s) Relative to Start Date		Day(s) Relative to Start Date		Day(s) Relative to Start Date		Day(s) Relative to Start Date		
	Posture	Gait	Gait	Gait	Gait	Gait	Gait	Gait	DeClInObs (Open Field Obs)		DeClInObs (Open Field Obs)		DeClInObs (Open Field Obs)		DeClInObs (Open Field Obs)		DeClInObs (Open Field Obs)		
									Locomotion	Dejection	Locomotion	Dejection	Locomotion	Dejection	Locomotion	Dejection	Locomotion	Dejection	
	38	0	0	7	14	0	7	21	28	0	7	14	21	28	0	7	14	21	28
7071	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7072	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7073	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7074	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7075	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7076	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7077	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7078	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7079	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7080	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

1536 µg/kg/day Group 4	Det/ClinObs (Open Field Obs)														
	Defecation	Defecation	Urination	Urination	Urination	Urination	Urination	Urination	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Unusual Behaviors	Vocalization (OF)	Vocalization (OF)
	21	28	0	7	14	21	28	0	7	14	21	28	0	7	
7071	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7072	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7073	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7074	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7075	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7076	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7077	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7078	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7079	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7080	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Individual Animal Detailed Clinical Observations  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

US36 mp/sg/day Group 4	Det Clin Obs (Open Field Obs) Vocalization (OF)		Vocalization (OF)	
	1-4	21	28	28
7071	0	0	0	0
7072	0	0	0	0
7073	0	0	0	0
7074	0	0	0	0
7075	0	0	0	0
7076	0	0	0	0
7077	0	0	0	0
7078	0	0	0	0
7079	0	0	0	0
7080	0	0	0	0

## APPENDIX I: INDIVIDUAL ANIMAL BODY WEIGHTS<sup>1</sup>

### PRODUCT IDENTIFICATION

Soy Leghemoglobin Preparation

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<sup>1</sup> Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Individual Animal Body Weights

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Bodyweight (g)

0 mg/kg/day Group I	Day(s) Relative to Start Date				
	0	7	14	21	28
7001	240	297	345	396	429
7002	232	273	327	362	382
7003	238	288	334	379	401
7004	234	271	310	343	360
7005	228	267	305	340	357
7006	247	303	347	404	434
7007	242	308	358	400	430
7008	230	283	328	361	379
7009	241	297	342	381	400
7010	232	290	327	366	375
Mean	236.4	287.7	332.3	373.2	394.7
SD	6.1	14.0	16.5	22.7	28.8
N	10	10	10	10	10

Individual Animal Body Weights

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Bodyweight (g)

S12 mg/kg/day Group 2	Day(s) Relative to Start Date				
	0	7	14	21	28
7021	232	284	324	363	390
7022	236	295	346	383	403
7023	243	299	353	392	415
7024	246	298	346	383	400
7025	237	291	331	369	387
7026	232	288	345	381	403
7027	240	291	330	374	398
7028	228	273	309	341	355
7029	241	306	370	421	458
7030	229	271	316	359	380
Mean	236.4	289.6	337.0	376.6	398.9
SD	6.1	11.1	18.4	21.4	26.4
N	10	10	10	10	10

Individual Animal Body Weights

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Male Bodyweight (g)

1024 mg/kg/day Group 3	Day(s) Relative to Start Date				
	0	7	14	21	28
7041	238	281	333	377	402
7042	250	306	367	419	448
7043	232	282	322	366	382
7044	231	295	353	401	434
7045	233	288	337	378	401
7046	244	308	371	415	448
7047	239	304	360	406	433
7048	241	303	360	411	445
7049	232	270	309	337	364
7050	227	272	304	335	345
Mean	236.7	290.9	341.6	384.5	410.2
SD	7.0	14.3	24.2	31.1	37.2
N	10	10	10	10	10



Individual Animal Body Weights  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Bodyweight (g)

1536 mg/kg/day Group 4	Day(s) Relative to Start Date					
	0	7	14	21	28	
7061	241	295	342	380	404	
7062	234	288	335	374	403	
7063	233	270	305	345	369	
7064	240	304	363	418	446	
7065	246	308	362	404	432	
7066	239	299	351	396	421	
7067	241	306	355	394	420	
7068	226	281	326	362	385	
7069	229	293	326	360	379	
7070	231	284	330	366	396	
Mean	236.3	292.8	339.5	379.9	405.5	
SD	6.7	12.2	18.6	22.7	24.4	
N	10	10	10	10	10	

Individual Animal Body Weights

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Bodyweight (g)

0 mg/kg/day Group 1	Day(s) Relative to Start Date				
	0	7	14	21	28
7011	165	178	188	204	208
7012	163	188	204	223	228
7013	197	210	261	282	288
7014	187	222	220 <sup>1</sup>	249	253
7015	181	205	217	243	252
7016	169	195	212	225	250
7017	156	176	192	209	223
7018	175	201	224	255	262
7019	180	212	239	244	264
7020	168	196	231	258	270
Mean	174.1	198.3	218.8	239.2	249.8
SD	12.3	14.8	21.9	24.0	24.0
N	10	10	10	10	10

<sup>1</sup> [RC:Reweighed, food and water OK]

Individual Animal Body Weights

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Bodyweight (g)

512 mg/kg/day Group 2	Day(s) Relative to Start Date				
	0	7	14	21	28
7031	192	217	239	246	257
7032	175	195	208	224	237
7033	173	200	210	228 <sup>1</sup>	238
7034	162	183	198	208	219
7035	168	194	218	229	244
7036	168	202	218	233	249
7037	153	169	182	187	196
7038	193	220	236	250	265
7039	183	215	241	240 <sup>2</sup>	260
7040	177	215	235	246	275
Mean	174.4	201.0	218.5	229.1	244.0
SD	12.6	16.5	19.6	19.4	23.3
N	10	10	10	10	10

1 [RC:Reweighed, food and water OK]

2 [RC:Reweighed, food and water OK]

Individual Animal Body Weights

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Bodyweight (g)

1024 mg/kg/day Group 3	Day(s) Relative to Start Date				
	0	7	14	21	28
7051	162	189	202	210	229
7052	162	192	216	224	238
7053	182	210	231	249	267
7054	189	216	239	255	267
7055	198	224	236	268	277
7056	176	214	239	257	266
7057	166	185	204	221	237
7058	169	198	215	228	237
7059	180	214	238	251	270
7060	172	198	217	225	244
Mean	175.6	204.0	223.7	238.8	253.2
SD	11.8	13.3	14.6	19.4	17.7
N	10	10	10	10	10

Individual Animal Body Weights  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female	Bodyweight (g)	Day(s) Relative to Start Date				
		0	7	14	21	28
1536						
mg/kg/day Group 4						
7071	171	198	212	240	248	
7072	168	196	218	229	246	
7073	181	208	232	244	263	
7074	179	195	215	229	234	
7075	177	201	218	229	241	
7076	163	190	219	242	245	
7077	187	215	241	260	271	
7078	162	191	213	224	237	
7079	196	215	246	258	262	
7080	159	184	199	225	240	
Mean	174.3	199.3	221.3	238.0	248.7	
SD	11.9	10.5	14.3	13.1	12.4	
N	10	10	10	10	10	

## APPENDIX J: INDIVIDUAL ANIMAL MEAN DAILY BODY WEIGHT GAIN<sup>1</sup>

### PRODUCT IDENTIFICATION

Soy Leghemoglobin Preparation

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<sup>1</sup> Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Individual Animal Mean Daily Body Weight Gain

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Mean Daily Body Weight Gain (g/day)

0 mg/kg/day Group 1	Day(s) Relative to Start Date						
	0 → 7	7 → 14	14 → 21	21 → 28	0 → 28	0 → 28	0 → 28
7001	8.1	6.9	7.3	4.7	6.8		
7002	5.9	7.7	5.0	2.9	5.4		
7003	7.1	6.6	6.4	3.1	5.8		
7004	5.3	5.6	4.7	2.4	4.5		
7005	5.6	5.4	5.0	2.4	4.6		
7006	8.0	6.3	8.1	4.3	6.7		
7007	9.4	7.1	6.0	4.3	6.7		
7008	7.6	6.4	4.7	2.6	5.3		
7009	8.0	6.4	5.6	2.7	5.7		
7010	8.3	5.3	5.6	1.3	5.1		
Mean	7.33	6.37	5.84	3.07	5.65		
SD	1.35	0.77	1.15	1.06	0.84		
N	10	10	10	10	10		

Individual Animal Mean Daily Body Weight Gain

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Mean Daily Body Weight Gain (g/day)

512 mg/kg/day Group 2	Dny(s) Relative to Start Date				
	0 → 7	7 → 14	14 → 21	21 → 28	0 → 28
7021	7.4	5.7	5.6	3.9	5.6
7022	8.4	7.3	5.3	2.9	6.0
7023	8.0	7.7	5.6	3.3	6.1
7024	7.4	6.9	5.3	2.4	5.5
7025	7.7	5.7	5.4	2.6	5.4
7026	8.0	8.1	5.1	3.1	6.1
7027	7.3	5.6	6.3	3.4	5.6
7028	6.4	5.1	4.6	2.0	4.5
7029	9.3	9.1	7.3	5.3	7.8
7030	6.0	6.4	6.1	3.0	5.4
Mean	7.60	6.77	5.66	3.19	5.80
SD	0.94	1.30	0.75	0.91	0.83
N	10	10	10	10	10



Individual Animal Mean Daily Body Weight Gain

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Mean Daily Body Weight Gain (g/day)

1024 mg/kg/day Group 3	Day(s) Relative to Start Date						
	0 → 7	7 → 14	14 → 21	21 → 28	0 → 28		
7041	6.1	7.4	6.3	3.6	5.9		
7042	8.0	8.7	7.4	4.1	7.1		
7043	7.1	5.7	6.3	2.3	5.4		
7044	9.1	8.3	6.9	4.7	7.3		
7045	7.9	7.0	5.9	3.3	6.0		
7046	9.1	9.0	6.3	4.7	7.3		
7047	9.3	8.0	6.6	3.9	6.9		
7048	8.9	8.1	7.3	4.9	7.3		
7049	5.4	5.6	4.0	3.9	4.7		
7050	6.4	4.6	4.4	1.4	4.2		
Mean	7.74	7.24	6.13	3.67	6.20		
SD	1.40	1.49	1.12	1.10	1.14		
N	10	10	10	10	10		

Individual Animal Mean Daily Body Weight Gain  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Mean Daily Body Weight Gain (g/day)

1536 mg/kg/day Group 4	Days Relative to Start Date						
	0 → 7	7 → 14	14 → 21	21 → 28	0 → 28	0 → 28	0 → 28
7061	7.7	6.7	5.4	3.4	5.8		
7062	7.7	6.7	5.6	4.1	6.0		
7063	5.3	5.0	5.7	3.4	4.9		
7064	9.1	8.4	7.9	4.0	7.4		
7065	8.9	7.7	6.0	4.0	6.6		
7066	8.6	7.4	6.4	3.6	6.5		
7067	8.9	7.0	5.6	3.7	6.3		
7068	7.9	6.4	5.1	3.3	5.7		
7069	9.1	4.7	4.9	2.7	5.4		
7070	7.6	6.6	5.1	4.3	5.9		
Mean	8.07	6.67	5.77	3.66	6.04		
SD	1.16	1.13	0.86	0.47	0.70		
N	10	10	10	10	10		

Individual Animal Mean Daily Body Weight Gain

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Mean Daily Body Weight Gain (g/day)

0 mg/kg/day Group 1	Day(s) Relative to Start Date				
	0 → 7	7 → 14	14 → 21	21 → 28	0 → 28
7011	1.9	1.4	2.3	0.6	1.5
7012	3.6	2.3	2.7	0.7	2.3
7013	1.9	7.3	3.0	0.9	3.3
7014	5.0	-0.3	4.1	0.6	2.4
7015	3.4	1.7	3.7	1.3	2.5
7016	3.7	2.4	1.9	3.6	2.9
7017	2.9	2.3	2.4	2.0	2.4
7018	3.7	3.3	4.4	1.0	3.1
7019	4.6	3.9	0.7	2.9	3.0
7020	4.0	5.0	3.9	1.7	3.6
Mean	3.46	2.93	2.91	1.51	2.70
SD	1.03	2.09	1.15	1.03	0.60
N	10	10	10	10	10

Individual Animal Mean Daily Body Weight Gain

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Mean Daily Body Weight Gain (g/day)

512 mg/kg/day Group 2	Day(s) Relative to Start Date				
	0 → 7	7 → 14	14 → 21	21 → 28	0 → 28
7031	3.6	3.1	1.0	1.6	2.3
7032	2.9	1.9	2.3	1.9	2.2
7033	3.9	1.4	2.6	1.4	2.3
7034	3.0	2.1	1.4	1.6	2.0
7035	3.7	3.4	1.6	2.1	2.7
7036	4.9	2.3	2.1	2.3	2.9
7037	2.3	1.9	0.7	1.3	1.5
7038	3.9	2.3	2.0	2.1	2.6
7039	4.6	3.7	-0.1	2.9	2.8
7040	5.4	2.9	1.6	4.1	3.5
Mean	3.80	2.50	1.51	2.13	2.49
SD	0.96	0.75	0.82	0.85	0.53
N	10	10	10	10	10

Individual Animal Mean Daily Body Weight Gain

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Mean Daily Body Weight Gain (g/day)

1024 mg/kg/day Group 3	Day(s) Relative to Start Date				
	0 → 7	7 → 14	14 → 21	21 → 28	0 → 28
7051	3.9	1.9	1.1	2.7	2.4
7052	4.3	3.4	1.1	2.0	2.7
7053	4.0	3.0	2.6	2.6	3.0
7054	3.9	3.3	2.3	1.7	2.8
7055	3.7	1.7	4.6	1.3	2.8
7056	5.4	3.6	2.6	1.3	3.2
7057	2.7	2.7	2.4	2.3	2.5
7058	4.1	2.4	1.9	1.3	2.4
7059	4.9	3.4	1.9	2.7	3.2
7060	3.7	2.7	1.1	2.7	2.6
Mean	4.06	2.81	2.16	2.06	2.77
SD	0.72	0.66	1.03	0.63	0.30
N	10	10	10	10	10

Individual Animal Mean Daily Body Weight Gain

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Mean Daily Body Weight Gain (g/day)

1536 mg/kg/day Group 4	Day(s) Relative to Start Date				
	0 → 7	7 → 14	14 → 21	21 → 28	0 → 28
7071	3.9	2.0	4.0	1.1	2.8
7072	4.0	3.1	1.6	2.4	2.8
7073	3.9	3.4	1.7	2.7	2.9
7074	2.3	2.9	2.0	0.7	2.0
7075	3.4	2.4	1.6	1.7	2.3
7076	3.9	4.1	3.3	0.4	2.9
7077	4.0	3.7	2.7	1.6	3.0
7078	4.1	3.1	1.6	1.9	2.7
7079	2.7	4.4	1.7	0.6	2.4
7080	3.6	2.1	3.7	2.1	2.9
Mean	3.57	3.14	2.39	1.53	2.66
SD	0.61	0.81	0.96	0.79	0.34
N	10	10	10	10	10

## APPENDIX K: INDIVIDUAL ANIMAL MEAN DAILY FOOD CONSUMPTION<sup>1</sup>

### PRODUCT IDENTIFICATION

Soy Leghemoglobin Preparation

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<sup>1</sup> Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Individual Animal Mean Daily Food Consumption

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Mean Daily Food Consumption (g/day)

0 mg/kg/day Group 1	Day(s) Relative to Start Date							
	3 → 7	7 → 10	10 → 14	14 → 17	17 → 21	21 → 24	24 → 28	3 → 28
7001	28.0	27.3	27.0	27.3	27.9	22.3	29.3	27.2
7002	28.0	27.3	27.0	27.3	27.9	22.3	29.3	27.2
7003	27.0	24.5	26.3	24.8	25.1	20.8	26.5	25.2
7004	27.0	24.5	26.3	24.8	25.1	20.8	26.5	25.2
7005	28.1	25.2	24.6	25.3	25.9	21.8	27.6	25.7
7006	28.1	25.2	24.6	25.3	25.9	21.8	27.6	25.7
7007	29.9	27.7	28.0	26.0	26.8	22.8	28.3	27.2
7008	29.9	27.7	28.0	26.0	26.8	22.8	28.3	27.2
7009	27.1	26.8	26.9	26.0	26.3	21.2	26.9	26.0
7010	27.1	26.8	26.9	26.0	26.3	21.2	26.9	26.0
Mean	28.03	26.30	26.55	25.90	26.38	21.80	27.70	26.26
SD	1.08	1.31	1.17	0.89	0.97	0.77	1.04	0.86
N	10	10	10	10	10	10	10	10



Individual Animal Mean Daily Food Consumption

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Mean Daily Food Consumption (g/day)

512 mg/kg/day Group 2	Day(s) Relative to Start Date							
	3 → 7	7 → 10	10 → 14	14 → 17	17 → 21	21 → 24	24 → 28	3 → 28
7021	28.8	26.2	26.9	25.2	25.9	21.5	27.6	26.2
7022	28.8	26.2	26.9	25.2	25.9	21.5	27.6	26.2
7023	29.4	27.5	27.6	25.0	26.4	21.5	27.5	26.6
7024	29.4	27.5	27.6	25.0	26.4	21.5	27.5	26.6
7025	28.8	27.8	27.4	24.0	26.5	21.8	29.3	26.7
7026	28.8	27.8	27.4	24.0	26.5	21.8	29.3	26.7
7027	28.1	26.2	25.9	24.3	25.9	21.5	28.8	26.0
7028	28.1	26.2	25.9	24.3	25.9	21.5	28.8	26.0
7029	28.0	27.8	28.5	28.8	27.9	24.0	30.6	28.1
7030	28.0	27.8	28.5	28.8	27.9	24.0	30.6	28.1
Mean	28.60	27.10	27.25	25.47	26.50	22.07	28.75	26.73
SD	0.52	0.81	0.91	1.83	0.77	1.03	1.21	0.76
N	10	10	10	10	10	10	10	10

Individual Animal Mean Daily Food Consumption

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Mean Daily Food Consumption (g/day)

1024 mg/kg/day Group 3	Day(s) Relative to Start Date							
	3 → 7	7 → 10	10 → 14	14 → 17	17 → 21	21 → 24	24 → 28	3 → 28
7041	28.3	29.0	29.5	29.5	29.3	23.0	30.6	28.6
7042	28.3	29.0	29.5	29.5	29.3	23.0	30.6	28.6
7043	29.8	27.8	27.6	27.8	27.1	22.0	28.4	27.4
7044	29.8	27.8	27.6	27.8	27.1	22.0	28.4	27.4
7045	30.0	29.0	29.8	25.2	27.5	24.3	30.3	28.2
7046	30.0	29.0	29.8	25.2	27.5	24.3	30.3	28.2
7047	28.6	29.0	28.6	27.2	28.6	22.3	30.5	28.0
7048	28.6	29.0	28.6	27.2	28.6	22.3	30.5	28.0
7049	24.5	24.2	23.9	22.0	23.0	19.7	25.9	23.5
7050	24.5	24.2	23.9	22.0	23.0	19.7	25.9	23.5
Mean	28.23	27.80	27.88	26.33	27.10	22.27	29.13	27.14
SD	2.08	1.97	2.25	2.71	2.31	1.61	1.92	1.98
N	10	10	10	10	10	10	10	10

Individual Animal Mean Daily Food Consumption

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Mean Daily Food Consumption (g/day)

1536 mg/kg/day Group 4	Day(s) Relative to Start Date							
	3 → 7	7 → 10	10 → 14	14 → 17	17 → 21	21 → 24	24 → 28	3 → 28
7061	27.8	27.7	26.8	26.2	25.6	21.3	28.1	26.3
7062	27.8	27.7	26.8	26.2	25.6	21.3	28.1	26.3
7063	28.5	27.7	26.4	25.3	27.5	23.2	27.5	26.7
7064	28.5	27.7	26.4	25.3	27.5	23.2	27.5	26.7
7065	29.4	27.7	28.6	26.7	27.9	22.8	30.1	27.8
7066	29.4	27.7	28.6	26.7	27.9	22.8	30.1	27.8
7067	30.1	29.3	28.6	27.3	27.3	22.7	30.8	28.2
7068	30.1	29.3	28.6	27.3	27.3	22.7	30.8	28.2
7069	27.4	27.2	26.9	25.3	26.4	22.3	29.4	26.6
7070	27.4	27.2	26.9	25.3	26.4	22.3	29.4	26.6
Mean	28.63	27.90	27.45	26.17	25.93	22.47	29.18	27.13
SD	1.07	0.78	1.03	0.82	0.85	0.65	1.28	0.78
N	10	10	10	10	10	10	10	10

Individual Animal Mean Daily Food Consumption

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Female Mean Daily Food Consumption (g/day)

0 mg/kg/day Group 1	Day(s) Relative to Start Date							
	3 → 7	7 → 10	10 → 14	14 → 17	17 → 21	21 → 24	24 → 28	3 → 28
7011	19.9	17.3	17.8	18.0	17.4	14.8	18.4	17.8
7012	19.9	17.3	17.8	18.0	17.4	14.8	18.4	17.8
7013	22.4	23.2	21.6	21.7	22.3	16.2	21.3	21.3
7014	22.4	23.2	21.6	21.7	22.3	16.2	21.3	21.3
7015	22.1	18.3	19.0	18.7	19.6	16.5	21.3	19.5
7016	22.1	18.3	19.0	18.7	19.6	16.5	21.3	19.5
7017	21.9	17.8	18.4	18.7	19.3	15.3	20.4	19.0
7018	21.9	17.8	18.4	18.7	19.3	15.3	20.4	19.0
7019	19.6	20.0	21.0	19.3	20.9	16.7	22.3	20.1
7020	19.6	20.0	21.0	19.3	20.9	16.7	22.3	20.1
Mean	21.18	19.33	19.55	19.27	19.88	15.90	20.70	19.55
SD	1.24	2.23	1.59	1.34	1.72	0.74	1.38	1.24
N	10	10	10	10	10	10	10	10

Individual Animal Mean Daily Food Consumption

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Mean Daily Food Consumption (g/day)

512 mg/kg/day Group 2	Day(s) Relative to Start Date							
	3 → 7	7 → 10	10 → 14	14 → 17	17 → 21	21 → 24	24 → 28	3 → 28
7031	22.1	19.0	23.8	20.5	19.9	16.2	23.5	21.0
7032	22.1	19.0	23.8	20.5	19.9	16.2	23.5	21.0
7033	20.3	18.2	18.3	20.0	19.0	15.3	20.9	19.0
7034	20.3	18.2	18.3	20.0	19.0	15.3	20.9	19.0
7035	20.3	18.3	18.9	18.7	19.0	16.0	20.1	18.9
7036	20.3	18.3	18.9	18.7	19.0	16.0	20.1	18.9
7037	22.9	17.7	20.6	18.8	22.0	16.3	19.9	20.0
7038	22.9	17.7	20.6	18.8	22.0	16.3	19.9	20.0
7039	20.6	19.0	20.8	19.0	20.5	17.3	22.3	20.1
7040	20.6	19.0	20.8	19.0	20.5	17.3	22.3	20.1
Mean	21.23	18.43	20.45	19.40	20.08	16.23	21.33	19.78
SD	1.13	0.54	2.02	0.76	1.18	0.68	1.44	0.82
N	10	10	10	10	10	10	10	10

Individual Animal Mean Daily Food Consumption

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Mean Daily Food Consumption (g/day)

1024 mg/kg/day Group 3	Day(s) Relative to Start Date							
	3 → 7	7 → 10	10 → 14	14 → 17	17 → 21	21 → 24	24 → 28	3 → 28
7051	20.9	17.5	18.4	17.7	17.3	15.8	20.5	18.4
7052	20.9	17.5	18.4	17.7	17.3	15.8	20.5	18.4
7053	22.0	19.7	20.6	19.5	20.8	15.5	22.3	20.3
7054	22.0	19.7	20.6	19.5	20.8	15.5	22.3	20.3
7055	22.9	23.2	20.4	20.0	20.6	16.3	21.4	20.8
7056	22.9	23.2	20.4	20.0	20.6	16.3	21.4	20.8
7057	19.9	17.2	18.0	16.8	18.0	15.8	19.8	18.1
7058	19.9	17.2	18.0	16.8	18.0	15.8	19.8	18.1
7059	19.6	19.0	19.9	18.3	20.1	16.3	21.5	19.4
7060	19.6	19.0	19.9	18.3	20.1	16.3	21.5	19.4
Mean	21.05	19.30	19.45	18.47	19.35	15.97	21.08	19.40
SD	1.31	2.26	1.12	1.22	1.52	0.34	0.91	1.09
N	10	10	10	10	10	10	10	10

Individual Animal Mean Daily Food Consumption

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Mean Daily Food Consumption (g/day)

1536 mg/kg/day Group 4	Day(s) Relative to Start Date							
	3 → 7	7 → 10	10 → 14	14 → 17	17 → 21	21 → 24	24 → 28	3 → 28
7071	19.8	17.2	17.0	17.8	18.1	14.7	20.8	18.1
7072	19.8	17.2	17.0	17.8	18.1	14.7	20.8	18.1
7073	21.1	19.2	19.6	17.0	19.9	16.2	19.6	19.1
7074	21.1	19.2	19.6	17.0	19.9	16.2	19.6	19.1
7075	20.5	19.3	19.5	19.5	19.0	16.0	21.1	19.4
7076	20.5	19.3	19.5	19.5	19.0	16.0	21.1	19.4
7077	20.5	19.8	19.4	19.7	19.6	15.7	20.1	19.4
7078	20.5	19.8	19.4	19.7	19.6	15.7	20.1	19.4
7079	19.0	19.0	19.9	19.7	19.0	15.7	20.6	19.1
7080	19.0	19.0	19.9	19.7	19.0	15.7	20.6	19.1
Mean	20.18	18.90	19.08	18.73	19.13	15.63	20.45	19.00
SD	0.77	0.96	1.11	1.17	0.64	0.55	0.55	0.52
N	10	10	10	10	10	10	10	10

## APPENDIX L: INDIVIDUAL ANIMAL FOOD EFFICIENCY<sup>1,2</sup>

### PRODUCT IDENTIFICATION

Soy Leghemoglobin Preparation

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<sup>1</sup> Food efficiency =  $\frac{\text{Mean Daily Body Weight Gain}}{\text{Mean Daily Food Consumption}}$

<sup>2</sup> Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.



Individual Animal Mean Food Efficiency

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Male Food Efficiency

0 mg/kg/day Group 1	Day(s) Relative to Start Date			
	0 → 7	7 → 14	14 → 21	21 → 28
7001	0.36	0.25	0.26	0.18
7002	0.26	0.28	0.18	0.11
7003	0.32	0.26	0.26	0.13
7004	0.24	0.22	0.19	0.10
7005	0.24	0.22	0.19	0.10
7006	0.34	0.25	0.32	0.17
7007	0.36	0.26	0.23	0.17
7008	0.29	0.23	0.18	0.10
7009	0.31	0.24	0.21	0.11
7010	0.32	0.20	0.21	0.05
Mean	0.304	0.241	0.223	0.121
SD	0.046	0.025	0.044	0.040
N	10	10	10	10

Individual Animal Mean Food Efficiency  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Food Efficiency

512 mg/kg/day Group 2	Day(s) Relative to Start Date				
	0 → 7	7 → 14	14 → 21	21 → 28	
7021	0.31	0.22	0.22	0.15	
7022	0.35	0.27	0.21	0.11	
7023	0.33	0.28	0.22	0.13	
7024	0.31	0.25	0.20	0.10	
7025	0.32	0.21	0.21	0.10	
7026	0.33	0.30	0.20	0.12	
7027	0.30	0.21	0.25	0.13	
7028	0.27	0.20	0.18	0.08	
7029	0.36	0.32	0.26	0.19	
7030	0.23	0.23	0.22	0.11	
Mean	0.312	0.248	0.217	0.123	
SD	0.038	0.043	0.022	0.032	
N	10	10	10	10	

Individual Animal Mean Food Efficiency

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Food Efficiency

1024 mg/kg/day Group 3	Day(s) Relative to Start Date			
	0 → 7	7 → 14	14 → 21	21 → 28
7041	0.27	0.25	0.21	0.13
7042	0.35	0.30	0.25	0.15
7043	0.30	0.21	0.23	0.09
7044	0.38	0.30	0.25	0.18
7045	0.31	0.24	0.22	0.12
7046	0.37	0.31	0.24	0.17
7047	0.37	0.28	0.23	0.14
7048	0.35	0.28	0.26	0.18
7049	0.23	0.23	0.18	0.17
7050	0.27	0.19	0.20	0.06
Mean	0.319	0.258	0.227	0.139
SD	0.051	0.041	0.026	0.040
N	10	10	10	10

Individual Animal Mean Food Efficiency

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Food Efficiency

1536 mg/kg/dny Group 4	Day(s) Relative to Start Date			
	0 → 7	7 → 14	14 → 21	21 → 28
7061	0.34	0.25	0.21	0.14
7062	0.34	0.25	0.22	0.16
7063	0.23	0.19	0.22	0.13
7064	0.40	0.31	0.30	0.16
7065	0.35	0.27	0.22	0.15
7066	0.34	0.26	0.23	0.13
7067	0.33	0.24	0.20	0.14
7068	0.29	0.22	0.19	0.12
7069	0.36	0.17	0.19	0.10
7070	0.30	0.24	0.20	0.16
Mean	0.329	0.241	0.217	0.139
SD	0.046	0.040	0.031	0.019
N	10	10	10	10

Individual Animal Mean Food Efficiency

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Food Efficiency

0 mg/kg/day Group 1	Day(s) Relative to Start Date			
	0 → 7	7 → 14	14 → 21	21 → 28
7011	0.12	0.08	0.13	0.03
7012	0.22	0.13	0.15	0.04
7013	0.10	0.33	0.14	0.04
7014	0.27	-0.01	0.19	0.03
7015	0.19	0.09	0.19	0.07
7016	0.20	0.13	0.10	0.19
7017	0.16	0.13	0.13	0.11
7018	0.20	0.18	0.23	0.05
7019	0.25	0.19	0.04	0.14
7020	0.22	0.24	0.19	0.09
Mean	0.193	0.148	0.149	0.080
SD	0.055	0.093	0.057	0.052
N	10	10	10	10

Individual Animal Mean Food Efficiency

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Female Food Efficiency

512 mg/kg/day Group 2	Day(s) Relative to Start Date			
	0 → 7	7 → 14	14 → 21	21 → 28
7031	0.20	0.14	0.05	0.08
7032	0.16	0.09	0.11	0.09
7033	0.23	0.08	0.13	0.08
7034	0.18	0.12	0.07	0.08
7035	0.23	0.18	0.08	0.12
7036	0.29	0.12	0.11	0.12
7037	0.12	0.10	0.03	0.07
7038	0.21	0.12	0.10	0.12
7039	0.24	0.19	-0.01	0.14
7040	0.28	0.14	0.08	0.21
Mean	0.215	0.128	0.077	0.111
SD	0.052	0.037	0.042	0.041
N	10	10	10	10

Individual Animal Mean Food Efficiency  
PSL Study Number 43166  
A 28-Day Dieback Study in Rats

Sex: Female Food Efficiency

1024 mg/kg/day Group 3	Day(s) Relative to Start Date				
	0 → 7	7 → 14	14 → 21	21 → 28	
7051	0.23	0.10	0.07	0.15	
7052	0.25	0.19	0.07	0.11	
7053	0.21	0.15	0.13	0.13	
7054	0.21	0.16	0.11	0.09	
7055	0.19	0.08	0.22	0.07	
7056	0.28	0.17	0.13	0.07	
7057	0.16	0.15	0.14	0.13	
7058	0.25	0.14	0.11	0.07	
7059	0.27	0.18	0.10	0.14	
7060	0.20	0.11	0.06	0.14	
Mean	0.226	0.146	0.112	0.109	
SD	0.037	0.033	0.049	0.033	
N	10	10	10	10	

Individual Animal Mean Food Efficiency

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Female Food Efficiency

1536 mg/kg/day Group 4	Day(s) Relative to Start Date			
	0 → 7	7 → 14	14 → 21	21 → 28
7071	0.23	0.12	0.22	0.06
7072	0.24	0.18	0.09	0.13
7073	0.23	0.18	0.09	0.15
7074	0.14	0.15	0.11	0.04
7075	0.19	0.13	0.08	0.09
7076	0.22	0.21	0.17	0.02
7077	0.23	0.19	0.14	0.09
7078	0.23	0.16	0.08	0.10
7079	0.15	0.23	0.09	0.03
7080	0.19	0.11	0.19	0.12
Mean	0.206	0.165	0.126	0.083
SD	0.038	0.040	0.052	0.044
N	10	10	10	10



**APPENDIX M: INDIVIDUAL ANIMAL MEAN DAILY DIETARY INTAKE OF  
SOY LEGHEMOGLOBIN PREPARATION<sup>1</sup>**

**PRODUCT IDENTIFICATION**

Soy Leghemoglobin Preparation

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<sup>1</sup> Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Individual Animal Mean Dietary Intake  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Dietary Intake Variable (mg/kg/day)

mg/kg/day Group 1	Day(s) Relative to Start Date				
	0 -> 7	7 -> 14	14 -> 21	21 -> 28	0 -> 28
7001	0	0	0	0	0
7002	0	0	0	0	0
7003	0	0	0	0	0
7004	0	0	0	0	0
7005	0	0	0	0	0
7006	0	0	0	0	0
7007	0	0	0	0	0
7008	0	0	0	0	0
7009	0	0	0	0	0
7010	0	0	0	0	0
Mean	0.0	0.0	0.0	0.0	0.0
SD	0.0	0.0	0.0	0.0	0.0
N	10	10	10	10	10

Individual Animal Mean Dietary Intake

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Dietary Intake Variable (mg/kg/day)

512 mg/kg/day Group 2	Day(s) Relative to Start Date				
	0 -- 7	7 -- 14	14 -- 21	21 -- 28	0 -- 28
7021	482	544	512	492	480
7022	469	516	482	471	459
7023	468	526	476	458	456
7024	466	533	486	472	464
7025	480	551	500	511	484
7026	487	542	482	493	474
7027	474	521	493	492	468
7028	503	556	533	546	507
7029	489	519	492	468	463
7030	535	598	576	557	535
Mean	485.4	540.5	503.2	495.9	478.9
SD	20.9	24.5	30.7	33.2	24.7
N	10	10	10	10	10

Individual Animal Mean Dietary Intake.

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Male Dietary Intake Variable (mg/kg/day)

1024 mg/kg/day Group 3	Day(s) Relative to Start Date				
	0 → 7	7 → 14	14 → 21	21 → 28	0 → 28
7041	928	1188	1129	1034	1009
7042	866	1083	1020	929	919
7043	989	1142	1089	1010	1001
7044	967	1065	993	905	925
7045	1011	1172	1012	1048	1003
7046	954	1079	921	946	919
7047	981	1079	998	948	946
7048	979	1081	992	929	937
7049	992	1032	954	975	934
7050	998	1037	965	1006	952
Mean	966.5	1095.9	1007.2	973.0	954.7
SD	42.5	53.5	61.7	49.1	36.0
N	10	10	10	10	10

Individual Animal Mean Dietary Intake

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Dietary Intake Variable (mg/kg/day)

1536 mg/kg/day Group 4	Day(s) Relative to Start Date				
	0 → 7	7 → 14	14 → 21	21 → 28	0 → 28
7061	1338	1587	1463	1411	1373
7062	1374	1623	1489	1424	1397
7063	1435	1745	1669	1576	1516
7064	1327	1504	1389	1303	1302
7065	1421	1569	1458	1417	1388
7066	1463	1617	1496	1450	1425
7067	1529	1631	1488	1471	1449
7068	1659	1776	1620	1603	1576
7069	1516	1625	1544	1565	1487
7070	1537	1638	1521	1518	1469
Mean	1459.8	1631.5	1513.7	1473.9	1438.2
SD	103.0	78.9	81.1	92.5	78.6
N	10	10	10	10	10

Individual Animal Mean Dietary Intake  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Dietary Intake Variable (mg/kg/day)

mg/kg/day Group 1	Day(s) Relative to Start Date				
	0 → 7	7 → 14	14 → 21	21 → 28	0 → 28
7011	0	0	0	0	0
7012	0	0	0	0	0
7013	0	0	0	0	0
7014	0	0	0	0	0
7015	0	0	0	0	0
7016	0	0	0	0	0
7017	0	0	0	0	0
7018	0	0	0	0	0
7019	0	0	0	0	0
7020	0	0	0	0	0
Mean	0.0	0.0	0.0	0.0	0.0
SD	0.0	0.0	0.0	0.0	0.0
N	10	10	10	10	10

Individual Animal Mean Dietary Intake

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Dietary Intake Variable (mg/kg/day)

512 mg/kg/day Group 2	Day(s) Relative to Start Date				
	0 → 7	7 → 14	14 → 21	21 → 28	0 → 28
7031	451	550	484	480	480
7032	498	622	543	523	532
7033	472	513	517	470	481
7034	510	552	557	513	521
7035	480	523	491	460	476
7036	470	513	487	451	469
7037	608	637	652	568	601
7038	474	490	495	422	458
7039	505	506	481	477	481
7040	513	513	481	458	477
Mean	498.0	541.9	518.8	482.4	497.8
SD	43.5	49.9	53.9	41.9	42.8
N	10	10	10	10	10

Individual Animal Mean Dietary Intake.

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Dietary Intake Variable (mg/kg/day)

1024 mg/kg/day Group 3	Day(s) Relative to Start Date				
	0 -- 7	7 -- 14	14 -- 21	21 -- 28	0 -- 28
7051	1013	1082	1046	1087	1022
7052	1004	1037	980	1033	982
7053	1003	1077	1041	968	986
7054	971	1044	1012	957	963
7055	957	1102	999	910	956
7056	1035	1119	1015	948	998
7057	1004	1065	1018	1018	988
7058	960	1004	977	1003	956
7059	975	1014	979	955	948
7060	1038	1101	1083	1061	1035
Mean	995.9	1064.6	1015.1	994.0	983.4
SD	29.2	39.2	34.3	56.0	29.0
N	10	10	10	10	10



Individual Animal Mean Dietary Intake

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Dietary Intake Variable (mg/kg/day)

1536 mg/kg/day Group 4	Day(s) Relative to Start Date				
	0 → 7	7 → 14	14 → 21	21 → 28	0 → 28
7071	1411	1475	1479	1434	1402
7072	1431	1461	1496	1473	1418
7073	1350	1565	1455	1380	1388
7074	1405	1679	1560	1511	1489
7075	1504	1643	1597	1553	1524
7076	1610	1683	1548	1499	1534
7077	1391	1521	1456	1323	1376
7078	1584	1717	1670	1524	1573
7079	1421	1499	1421	1372	1384
7080	1703	1804	1690	1534	1618
Mean	1481.1	1604.6	1537.2	1460.2	1470.4
SD	115.0	116.7	92.3	79.0	88.2
N	10	10	10	10	10

## **APPENDIX N: CLINICAL PATHOLOGY**

### **PRODUCT IDENTIFICATION**

Soy Leghemoglobin Preparation

Submitted by:

Dupont Haskell Global Centers  
for Health and Environmental Sciences  
P.O. Box 30, Elkton Road  
Newark, Delaware 19714

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**STUDY TITLE:** Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in  
Rats

**AUTHOR:** Denise Hoban, B.A., MLT (ASCP)

**CLINICAL PATHOLOGY**

**RESULTS COMPLETED:** July 20, 2017

**PERFORMING LABORATORY:** E.I. du Pont de Nemours and Company  
DuPont Haskell Global Centers for  
Health & Environmental Sciences  
P.O. Box 30  
Newark, Delaware 19714  
U.S.A.

**WORK REQUEST NUMBER:** 21641

**SERVICE CODE NUMBER:** 1611

**CLIENT:** Product Safety Labs  
2394 U.S. Highway 130  
Dayton, New Jersey 08810  
U.S.A.

**CLIENT STUDY NUMBER:** 43166

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

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**GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT**

The work performed at DuPont Haskell was conducted in compliance with U.S. FDA (21 CFR part 58) Good Laboratory Practice Standards, which are compatible with current OECD Good Laboratory Practices.

**Client:** Product Safety Labs  
2394 U.S. Highway 130  
Dayton, New Jersey 08810  
U.S.A.

(b) (6)

Reported by: \_\_\_\_\_

Denise Hoban, B.A., MLT (ASCP)  
Senior Staff Toxicologist & Pathology Coordinator  
E.I. du Pont de Nemours and Company

20 July 2017  
Date

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

**QUALITY ASSURANCE STATEMENT**

Work Request Number: 21641  
Service Code Number: 1611  
PSL Study Number: 43166

Key inspections for the above referenced clinical pathology study were completed by the Quality Assurance Unit of DuPont Haskell and the findings were submitted on the following dates:

<u>Audit Dates</u>	<u>Date Reported to:</u>			
	<u>Principal Investigator (PI)</u>	<u>PI Management</u>	<u>Study Director (SD)</u>	<u>SD Management</u>
<u>Protocol/Conduct:</u> 20 October 2016	21 October 2016	21 October 2016	21 October 2016	21 October 2016
<u>Report/Records:</u> 29-30 November 2016	30 November 2016	30 November 2016	30 November 2016	30 November 2016
9 December 2016	9 December 2016	9 December 2016	9 December 2016	9 December 2016

Reported by: (b) (6)  
Jessica Garcia-Arbitet  
Quality Assurance Auditor

20 July 2017  
Date

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

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**CERTIFICATION**

I, the undersigned, declare that these results provide accurate data obtained from this study.

Issued by (b) (6)  
Principal Investigator: \_\_\_\_\_  
Denise Hoban, B.A., MLT (ASCP)  
Senior Staff Toxicologist & Pathology Coordinator

*20 July 2017*  
Date

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

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### STUDY DESIGN

A 28-day dietary study in rats was conducted at Product Safety Labs (Dayton, New Jersey, U.S.A.) on behalf of Impossible Foods, Inc. (Redwood City, California, U.S.A.). Groups of 10 male and 10 female rats were fed 0, 512, 1024, 1536 mg/kg/day Soy Leghemoglobin Preparation which corresponds to 0, 250, 500 and 750 mg/kg/day of active ingredient Soy Leghemoglobin. Samples were collected for clinical pathology evaluation on test days 22 and 29/30 and were shipped to DuPont Haskell for analysis.

### MATERIALS AND METHODS

Clinical pathology analyses were conducted on samples collected on test days 22 (hematology, clinical chemistry, and urinalysis) and test days 29 (males) and 30 (females) (coagulation). Hematology measurements were conducted on whole blood on the day of collection. Clinical chemistry and coagulation measurements were conducted on samples that were frozen until analysis. All blood samples were evaluated for quality by visual examination. Urinalysis measurements were conducted on the day of collection.

#### 1. Hematology and Coagulation

Complete blood counts, including reticulocytes, were determined on an Advia 120 Hematology Analyzer. Blood smears, stained with New Methylene-Blue or Wright-Giemsa, were prepared from each animal undergoing a hematology evaluation, but were not needed for examination. Coagulation times were determined on a Sysmex CA-1500 Coagulation Analyzer.

The following parameters were determined:

red blood cell count	red cell distribution width
hemoglobin	absolute reticulocyte count
hematocrit	platelet count
mean corpuscular (cell) volume	white blood cell count
mean corpuscular (cell) hemoglobin	differential white blood cell count
mean corpuscular (cell) hemoglobin concentration	
prothrombin time	activated partial thromboplastin time

#### 2. Clinical Chemistry

Serum clinical chemistry parameters were determined on an Olympus AU640 Clinical Chemistry Analyzer.

The following parameters were determined:

aspartate aminotransferase	glucose
alanine aminotransferase	total protein

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

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sorbitol dehydrogenase	albumin
alkaline phosphatase	globulin
total bilirubin	calcium
urea nitrogen	inorganic phosphorus
creatinine	sodium
cholesterol	potassium
triglycerides	chloride

### 3. Urinalysis

Urine volume was measured, and appearance (quality, color, and clarity) was evaluated visually. Urine protein was measured on an Olympus AU640 Clinical Chemistry Analyzer. Other urine constituents were semi-quantitatively measured on a Clinitek Atlas Automated Urine Chemistry analyzer. Sediments from urine specimens were evaluated microscopically.

The following parameters were determined:

quality	ketone
color	bilirubin
clarity	blood
volume	urobilinogen
specific gravity	protein
pH	microscopic urine sediment examination
glucose	



Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

### STATISTICAL ANALYSES

Significance was judged at  $p < 0.05$ . Separate analyses were performed on the data collected for each sex. Statistical analyses were performed by Provantis<sup>®</sup> (1)

Parameter	Preliminary Test	Method of Statistical Analysis	
		If preliminary test is not significant	If preliminary test is significant
Clinical Pathology <sup>a</sup>	Levene's test for homogeneity <sup>(2)</sup> and Shapiro-Wilk test <sup>(3)</sup> for normality	One-way analysis of variance <sup>(4)</sup> followed by Dunnett's test <sup>(5)</sup>	Transforms of the data to achieve normality and variance homogeneity were used. The order of transforms attempted was log, square-root, and rank-order. If the log and square-root transforms failed, the rank-order was used.

- a When an individual observation was recorded as being less than a certain value, calculations were performed on half the recorded value. For example, if bilirubin was reported as  $<0.10$ , 0.05 was used for any calculations performed with those bilirubin data. When an individual observation was recorded as being greater than a certain value, calculations were performed on the recorded value. For example, if specific gravity was reported as  $>1.100$ , 1.100 was used for any calculations performed with those specific gravity data.

### RECORDS AND SAMPLE STORAGE

For the work conducted at DuPont Haskell, specimens (if applicable), raw data, and the clinical pathology report will be returned to the client within 6 months after the final report issues.

### REFERENCES

1. Provantis<sup>®</sup> (2012). Tables and Statistics (version 8). Instem LSS, Staffordshire, U.K.
2. Levene, H. (1960). Robust test for equality of variances. *Contributions to Probability and Statistics* (J. Olkin, ed.), pp 278-292. Stanford University Press, Palo Alto.
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4. Snedecor, G.W. and Cochran, W.G. (1967). *Statistical Methods*, 6<sup>th</sup> edition, pp 246-248 and 349-352. The Iowa State University Press, Iowa.
5. Dunnett, C.W. (1964). New tables for multiple comparisons with a control. *Biometrics* **20**, 482-491.

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**TABLES**

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

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TABLES

EXPLANATORY NOTES

ABBREVIATIONS:

**General**

SD - standard deviation  
N - number of values used in calculation  
% Diff - percent difference from control  
. or - - no data

**Summary of Hematology Values**

RBC - red blood cell count  
HGB - hemoglobin  
HCT - hematocrit  
MCV - mean corpuscular (cell) volume  
MCH - mean corpuscular (cell) hemoglobin  
MCHC - mean corpuscular (cell) hemoglobin concentration  
RDW - red cell distribution width  
PLT - platelet count  
WBC - white blood cell count  
ANEU - absolute neutrophil (all forms)  
ALYM - absolute lymphocyte  
AMON - absolute monocyte  
AEOS - absolute eosinophil  
ABAS - absolute basophil  
ALUC - absolute large unstained cell  
ARET - absolute reticulocyte

**Summary of Coagulation Values**

PT - prothrombin time  
APTT - activated partial thromboplastin time

**Summary of Clinical Chemistry Values**

AST - aspartate aminotransferase  
ALT - alanine aminotransferase  
SDH - sorbitol dehydrogenase  
ALKP - alkaline phosphatase  
BILI - total bilirubin  
BUN - urea nitrogen  
CREA - creatinine  
CHOL - cholesterol  
TRIG - triglycerides  
GLUC - glucose  
TP - total protein  
ALB - albumin  
GLOB - globulin  
CALC - calcium  
IPHS - inorganic phosphorus  
NA - sodium  
K - potassium  
CL - chloride

**Summary of Urinalysis Values**

UVOL - volume  
pH - the logarithm of the reciprocal of the hydrogen ion concentration  
SG - specific gravity  
URO - urobilinogen  
UWPP - protein

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

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TABLES

EXPLANATORY NOTES (Continued)

ABBREVIATIONS: (Continued)

NOTES:

Summary of Hematology Values  
Summary of Coagulation Values  
Summary of Clinical Chemistry Values  
Summary of Urinalysis Values

Groups with identical values may vary in statistical significance, because tabulated statistics are rounded to fewer decimal places than the values used for statistical determination.

The calculation for %Diff (deviation from control) is as follows:

$\%Diff = ((\text{current group mean} - \text{control group mean}) / \text{control group mean}) \times 100$

This calculation is performed upon full precision means and not the rounded values displayed within this report.

Calculation of mean, SD, and %Diff may vary from computer-generated values due to differences in rounding.

Clinical Pathology Results for  
Soy Leghemoglobin Preparation A 28-Day Dietary Study in Rats

**Table 1**  
**Summary of Hematology Values for Male Rats**

Sex: Male			0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date						
RBC ( $\times 10^6/\mu\text{L}$ )	22	Mean	7.72	7.69	7.61	7.70
		SD	0.23	0.34	0.35	0.27
		N	10	10	10	10
		%Diff		-1.6	-1.5	-0.3
HGB (g/dL)	22	Mean	15.6	15.4	15.5	15.9
		SD	0.3	0.6	0.6	0.4
		N	10	10	10	10
		%Diff		-1.5	-1.0	1.4
HCT (%)	22	Mean	45.5	45.1	45.1	45.9
		SD	0.9	1.5	1.7	0.8
		N	10	10	10	10
		%Diff		-0.9	-0.8	1.0
MCV (fL)	22	Mean	59.9	59.3	59.3	59.7
		SD	1.0	2.3	1.5	1.9
		N	10	10	10	10
		%Diff		0.7	0.7	1.3
MCH (pg)	22	Mean	20.3	20.3	20.4	20.6
		SD	0.5	0.9	0.5	0.7
		N	10	10	10	10
		%Diff		0.2	0.6	1.0
MCHC (g/dL)	22	Mean	34.4	34.2	34.4	34.5
		SD	0.4	0.4	0.3	0.5
		N	10	10	10	10
		%Diff		-0.5	-0.1	0.4
RDW (%)	22	Mean	12.1	12.5	12.5	12.3
		SD	0.3	0.5	0.3	0.5
		N	10	10	10	10
		%Diff		3.0	3.3	1.6
PLT ( $\times 10^3/\mu\text{L}$ )	22	Mean	1160	1202	1171	1227
		SD	121	89	76	185
		N	10	10	10	10
		%Diff		3.6	1.0	5.8

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation: Automatic]

Group 2, 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3, 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4, 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

Table I  
Summary of Hematology Values for Male Rats (Continued)

Sex: Male	Day(s) Relative to Start Date		0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
WBC ( $\times 10^3/\mu\text{L}$ )	22	Mean	13.00	14.41	11.13	13.45
		SD	1.33	2.07	1.62	4.41
		N	10	10	10	10
		%Diff		10.8	-14.4	3.4
ANCU ( $\times 10^3/\mu\text{L}$ )	22	Mean	1.01	1.99	1.75	1.57
		SD	0.07	0.43	0.43	0.62
		N	10	10	10	10
		%Diff		4.1	-8.1	-17.8
ALYM ( $\times 10^3/\mu\text{L}$ )	22	Mean	10.49	11.79	8.06	11.29
		SD	1.17	2.48	1.70	4.15
		N	10	10	10	10
		%Diff		12.4	-15.5	7.7
AMCN ( $\times 10^3/\mu\text{L}$ )	22	Mean	0.31	0.34	0.28	0.30
		SD	0.10	0.11	0.05	0.10
		N	10	10	10	10
		%Diff		10.2	-9.8	-1.5
AEOS ( $\times 10^3/\mu\text{L}$ )	22	Mean	0.12	0.13	0.11	0.11
		SD	0.04	0.08	0.04	0.05
		N	10	10	10	10
		%Diff		4.4	-7.2	-7.6
ABAS ( $\times 10^3/\mu\text{L}$ )	22	Mean	0.09	0.09	0.07	0.10
		SD	0.03	0.04	0.02	0.06
		N	10	10	10	10
		%Diff		-5.0	-27.0	0.2
ALUC ( $\times 10^3/\mu\text{L}$ )	22	Mean	0.08	0.08	0.06	0.06
		SD	0.03	0.03	0.02	0.04
		N	10	10	10	10
		%Diff		-8.1	-27.0	-2.4
ARET ( $\times 10^3/\mu\text{L}$ )	22	Mean	232.6	235.8	246.3	243.8
		SD	31.2	40.7	24.1	41.1
		N	10	10	10	10
		%Diff		1.4	9.9	4.8

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation: Automatic]

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Clinical Pathology Results for  
Soy Leghemoglobin Preparation - A 28-Day Dietary Study in Rats

Table 2  
Summary of Hematology Values for Female Rats

Sex: Female			0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date						
RBC ( $\times 10^6/\mu\text{L}$ )	22	Mean	7.59	8.01 *	7.86	7.63
		SD	0.24	0.38	0.24	0.30
		N	10	10	10	10
		%Diff		5.8	3.6	0.6
HGB (g/dL)	22	Mean	15.3	16.2 *	15.7	15.5
		SD	0.5	0.5	0.4	0.6
		N	10	10	10	10
		%Diff		5.7	2.5	0.9
MCT (%)	22	Mean	43.0	45.9 *	44.7	44.0
		SD	1.2	1.2	1.3	1.7
		N	10	10	10	10
		%Diff		5.2	2.4	0.9
MCV (fL)	22	Mean	57.5	57.4	56.8	57.7
		SD	1.1	2.2	1.2	2.7
		N	10	10	10	10
		%Diff		-0.2	-1.1	0.4
MCH (pg)	22	Mean	20.2	20.2	20.0	20.3
		SD	0.3	0.7	0.5	0.7
		N	10	10	10	10
		%Diff		0.1	-1.0	0.3
MCHC (g/dL)	22	Mean	35.2	35.3	35.2	35.7
		SD	0.7	0.3	0.4	0.5
		N	10	10	10	10
		%Diff		0.3	0.1	0.9
RDW (%)	22	Mean	11.3	11.3	11.2	11.5
		SD	0.4	0.5	0.3	0.5
		N	10	10	10	10
		%Diff		0.1	-0.4	1.7
PLT ( $\times 10^3/\mu\text{L}$ )	22	Mean	1180	1176	1230	1220
		SD	108	127	115	114
		N	10	10	10	10
		%Diff		-1.1	3.4	3.3

General Footnote: [Statistical Test: ANOVA and Dunnett's test Transformation: Automatic]  
1) \* - Test: Dunnett 2 Sided p < 0.05

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Clinical Pathology Results for  
Soy Leghemoglobin Preparation A 28-Day Dietary Study in Rats

Table 2  
Summary of Hematology Values for Female Rats (Continued)

Sex: Female			0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date						
WBC (x10 <sup>3</sup> /µL)	22	Mean	10.08	11.67	11.59	10.10
		SD	1.70	1.75	3.35	3.72
		N	10	10	10	10
		%Diff		17.7	15.0	1.1
ANCU (x10 <sup>3</sup> /µL)	22	Mean	1.48	1.56	1.68	1.54
		SD	0.30	0.58	0.85	1.10
		N	10	10	10	10
		%Diff		5.3	13.9	4.0
ALYM (x10 <sup>3</sup> /µL)	22	Mean	8.15	9.74	9.29	8.71
		SD	1.58	1.43	2.71	2.88
		N	10	10	10	10
		%Diff		18.9	14.0	0.7
AMON (x10 <sup>3</sup> /µL)	22	Mean	0.25	0.29	0.33	0.22
		SD	0.15	0.08	0.15	0.14
		N	10	10	10	10
		%Diff		16.7	32.5	-11.1
AEOS (x10 <sup>3</sup> /µL)	22	Mean	0.11	0.13	0.15	0.12
		SD	0.03	0.04	0.05	0.06
		N	10	10	10	10
		%Diff		21.4	35.8	0.6
ABAS (x10 <sup>3</sup> /µL)	22	Mean	0.04	0.07	0.08	0.05
		SD	0.01	0.03	0.03	0.04
		N	10	10	10	10
		%Diff		93.2	64.1	46.7
ALUC (x10 <sup>3</sup> /µL)	22	Mean	0.05	0.07	0.07	0.05
		SD	0.02	0.02	0.03	0.04
		N	10	10	10	10
		%Diff		29.1	26.2	2.9
ARET (x10 <sup>3</sup> /µL)	22	Mean	205.8	182.4	168.1	184.2
		SD	33.9	32.9	30.9	33.7
		N	10	10	10	10
		%Diff		-11.3	-17.8	-10.5

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation: Auzarokis]

1 [0- Test Dunnett 2 Sided p < 0.05]

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.

Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.

Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.



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**Table 3**  
Summary of Coagulation Values for Male Rats

Sex: Male			0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date						
PT (sec)	29	Mean	10.7	10.7	10.6	10.8
		SD	0.3	0.4	0.2	0.2
		N	10	10	10	10
APTT (sec)	29	Mean	20.2	23.8	24.9 <sup>a</sup>	23.9 <sup>a</sup>
		SD	2.4	5.3	8.9	4.8
		N	10	10	10	10

General Footnote [Statistical Test: Anova and Dunnett's test Transformation: Automatic]  
f [a] - Test: Dunnett Non-Parametric 2 Sided p < 0.05

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Clinical Pathology Results for  
Soy Leghemoglobin Preparation. A 28-Day Dietary Study in Rats

**Table 4**  
**Summary of Coagulation Values for Female Rats**

Sex: Female			0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date						
PT (sec)	30	Mean	10.0	8.8	10.0	9.8
		SD	0.2	0.2	0.3	0.2
		N	10	10	10	10
APTT (sec)	30	Mean	21.0	20.0	20.8	19.4
		SD	2.5	3.1	5.0	1.8
		N	10	10	10	10

General Footnote [Statistical Test: Anova and Dunnett's test Transformation: Automatic]

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Clinical Pathology Results for  
Soy Leghemoglobin Preparation - A 28-Day Dietary Study in Rats

Table 5  
Summary of Clinical Chemistry Values for Male Rats

Sex: Male			0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date						
AST (U/L)	22	Mean	73	76	79	78
		SD	8	9	7	8
		N	5	9	6	8
		%Diff		4.0	7.5	6.9
ALT (U/L)	22	Mean	29	28	28	30
		SD	4	4	3	4
		N	10	10	10	10
		%Diff		-3.1	-2.4	2.4
SDH (U/L)	22	Mean	6.2	6.1	6.4	6.0
		SD	1.4	1.7	2.4	1.4
		N	5	9	6	8
		%Diff		-0.8	2.7	-1.9
ALP (U/L)	22	Mean	183	216	216	206
		SD	24	28	44	42
		N	10	10	10	10
		%Diff		18.6	18.5	12.3
BUN (mg/dL)	22	Mean	0.17	0.17	0.18	0.18
		SD	0.02	0.02	0.02	0.02
		N	10	10	10	10
		%Diff		1.2	4.1	5.9
BUN (mg/dL)	22	Mean	10	11	10	11
		SD	1	1	1	2
		N	10	10	10	10
		%Diff		4.9	-3.8	1.0
CREA (mg/dL)	22	Mean	0.22	0.23	0.23	0.21
		SD	0.01	0.02	0.02	0.02
		N	10	10	10	10
		%Diff		3.6	4.1	-5.9
CHOL (mg/dL)	22	Mean	76	73	72	67
		SD	16	27	14	12
		N	10	10	10	10
		%Diff		-3.4	-5.4	-11.7

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation: Automatic]

Group 2: 512 mg/kg/day of test substance corresponds to 256 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leghemoglobin Preparation A 28-Day Dietary Study in Rats

Table 5  
Summary of Clinical Chemistry Values for Male Rats (Continued)

Sex Male			0	512	1024	1536
Day(s) Relative to Start Date			mg/kg/day Group 1	mg/kg/day Group 2	mg/kg/day Group 3	mg/kg/day Group 4
TRIG (mg/dL)	22	Mean	66	67	67	68
		SD	17	13	17	28
		N	10	10	10	10
		%Diff		1.6	0.9	2.4
GLUC (mg/dL)	22	Mean	95	100	102	98
		SD	12	9	13	8
		N	10	10	10	10
		%Diff		5.4	7.1	2.6
TP (g/dL)	22	Mean	6.0	6.1	6.2	6.0
		SD	0.2	0.2	0.2	0.2
		N	10	10	10	10
		%Diff		0.7	2.8	0.2
ALB (g/dL)	22	Mean	3.1	3.2	3.3 *	3.2
		SD	0.1	0.1	0.1	0.1
		N	10	10	10	10
		%Diff		2.2	4.1	1.9
GLOB (g/dL)	22	Mean	2.9	2.8	2.9	2.8
		SD	0.1	0.2	0.1	0.2
		N	10	10	10	10
		%Diff		-1.0	1.4	-1.7
CALC (mg/dL)	22	Mean	10.4	10.4	10.4	10.5
		SD	0.2	0.2	0.2	0.2
		N	10	10	10	10
		%Diff		-0.1	0.1	0.8
IPHS (mg/dL)	22	Mean	8.6	8.7	8.6	8.6
		SD	0.4	0.4	0.9	0.4
		N	5	9	8	8
		%Diff		0.6	2.1	-0.3
NA (mmol/L)	22	Mean	140.5	142.1	141.1	141.7
		SD	4.2	0.6	0.7	0.8
		N	10	10	10	10
		%Diff		1.1	0.4	0.9

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation: Automatic]

1) #: Test Dunnett 2 Sided p < 0.05

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient

Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient

Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
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Table 5  
Summary of Clinical Chemistry Values for Male Rats (Continued)

Sex: Male			0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date						
K (mmol/L)	22	Mean	5.03	5.19	5.55	5.10
		SD	0.25	0.26	0.81	0.25
		N	10	10	10	10
		NDFF		3.1	10.4	1.4
CL (mmol/L)	22	Mean	100.8	102.0	101.8	101.7
		SD	2.4	1.0	0.8	1.2
		N	10	10	10	10
		NDFF		1.2	0.8	0.8

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation: Automatic]

[# - Test Dunnett 2 Sided p < 0.05]

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

**Table 6**  
**Summary of Clinical Chemistry Values for Female Rats**

Sex: Female			0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date						
AST (U/L)	22	Mean	69	68	64	65
		SD	6	10	8	6
		N	9	9	10	10
		%Diff		-0.3	-7.4	-8.5
ALT (U/L)	22	Mean	25	26	25	27
		SD	4	5	8	5
		N	10	10	10	10
		%Diff		2.8	-0.4	5.2
SDH (U/L)	22	Mean	8.7	8.1	8.0	9.9
		SD	2.2	1.2	0.9	2.5
		N	9	9	10	10
		%Diff		-7.4	-9.0	12.9
ALP (U/L)	22	Mean	137	107	121	108
		SD	16	18	29	25
		N	10	10	10	10
		%Diff		-22.4	-12.1	-21.2
BUN (mg/dL)	22	Mean	0.18	0.19	0.20	0.19
		SD	0.02	0.02	0.02	0.03
		N	10	10	10	10
		%Diff		8.4	10.6	7.8
BLIN (mg/dL)	22	Mean	12	11	12	12
		SD	2	1	2	1
		N	10	10	10	10
		%Diff		-11.5	-0.8	0.0
CREA (mg/dL)	22	Mean	0.28	0.26	0.27	0.28
		SD	0.02	0.02	0.03	0.03
		N	10	10	10	10
		%Diff		-6.9	-2.9	1.1
CHOL (mg/dL)	22	Mean	85	95	98	84
		SD	11	18	19	22
		N	10	10	10	10
		%Diff		12.2	15.6	11.7

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation: Automatic]  
1 #: Test Dunnett 2 Sided p < 0.05

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leghemoglobin Preparation - A 28-Day Dietary Study in Rats

Table 6  
Summary of Clinical Chemistry Values for Female Rats (Continued)

Sex: Female			0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date						
TRIG (mg/dL)	22	Mean	37	38	48	55
		SD	6	9	15	8
		N	10	10	10	10
		%Diff		3.5	24.9	-4.3
GLUC (mg/dL)	22	Mean	118	103 *	104 *	110
		SD	15	10	10	14
		N	10	10	10	10
		%Diff		-13.3	-12.0	-8.7
TP (g/dL)	22	Mean	6.4	6.7	6.8	6.7
		SD	0.3	0.4	0.3	0.4
		N	10	10	10	10
		%Diff		5.1	5.6	3.7
ALB (g/dL)	22	Mean	3.5	3.7	3.7	3.6
		SD	0.2	0.2	0.2	0.3
		N	10	10	10	10
		%Diff		4.0	4.6	3.4
GLOB (g/dL)	22	Mean	2.9	3.1 *	3.1 *	3.0
		SD	0.1	0.2	0.2	0.1
		N	10	10	10	10
		%Diff		6.6	6.9	4.1
CALC (mg/dL)	22	Mean	10.5	10.9 *	11.0 *	10.7
		SD	0.3	0.3	0.3	0.4
		N	10	10	10	10
		%Diff		3.8	5.1	1.8
BPHS (mg/dL)	22	Mean	7.1	7.8	7.6	7.1
		SD	0.5	0.6	0.4	0.8
		N	9	9	10	10
		%Diff		9.7	6.5	-0.6
NA (mmol/L)	22	Mean	140.3	140.6	140.3	140.2
		SD	1.1	0.6	0.7	1.1
		N	10	10	10	10
		%Diff		0.2	0.0	0.0

General Footnote [Statistical Test: Anova and Dunnett's test Transformation: Automatic]

1) \* - Test Dunnett 2 Sided p < 0.05

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient

Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient

Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

Table 6  
Summary of Clinical Chemistry Values for Female Rats (Continued)

Sex: Female			0	512	1024	1536
Day(s) Relative to Start Date			mg/kg/day Group 1	mg/kg/day Group 2	mg/kg/day Group 3	mg/kg/day Group 4
K (µmol/L)	22	Mean	4.56	4.03	4.72	4.74
		SD	0.33	0.38	0.21	0.38
		N	10	10	10	10
		NDFF		1.5	3.5	4.0
CL (µmol/L)	22	Mean	102.8	101.3 *	101.1 *	102.1
		SD	1.2	1.4	1.0	1.1
		N	10	10	10	10
		NDFF		-1.3	-1.5	-0.5

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation: Automatic]  
[\*] p < 0.05, Dunnett 2 Sided

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient



Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

Table 7  
Summary of Urinalysis Values for Male Rats

Sex: Male			0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date						
UVOL (mL)	22	Mean	11.7	11.5	12.3	14.3
		SD	8.2	9.8	7.3	7.7
		N	10	10	10	10
		%Diff		-1.8	4.8	22.0
pH	22	Mean	6.5	6.5	6.6	6.6
		SD	0.3	0.4	0.4	0.4
		N	10	9	10	10
		%Diff		0.0	0.0	1.5
SG	22	Mean	1.027	1.027	1.026	1.024
		SD	0.019	0.015	0.015	0.019
		N	10	9	10	10
		%Diff		0.0	-0.1	-0.3
URO (BUN/dL)	22	Mean	0.3	0.2	0.3	0.2
		SD	0.3	0.0	0.3	0.0
		N	10	9	10	10
		%Diff		-28.6	0.0	-28.6
UMTP (mg/dL)	22	Mean	104	241	124	111
		SD	48	365	80	97
		N	10	10	10	10
		%Diff		132.5	19.4	7.4

General Footnote: [Statistical Test: Anova and Dunnett's test Transformation: Automatic]

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

Table 8  
Summary of Urinalysis Values for Female Rats

Sex: Female			0 mg/kg/day Group 1	512 mg/kg/day Group 2	1024 mg/kg/day Group 3	1536 mg/kg/day Group 4
Day(s) Relative to Start Date						
UVCL (mL)	22	Mean	7.9	6.8	6.5	6.8
		SD	6.4	5.1	3.0	4.1
		N	10	10	10	10
		%Diff		-12.1	-15.9	-14.9
pH	22	Mean	6.4	6.2	6.6	6.5
		SD	0.4	0.4	0.6	0.6
		N	10	10	10	10
		%Diff		-3.9	3.1	0.6
SG	22	Mean	1.037	1.035	1.028	1.030
		SD	0.027	0.023	0.011	0.013
		N	10	10	10	10
		%Diff		-0.2	-0.6	-0.6
URO (EUM/L)	22	Mean	0.2	0.2	0.2	0.3
		SD	0.0	0.0	0.0	0.3
		N	10	10	10	10
		%Diff		0.0	0.0	66.0
UMTP (mg/dL)	22	Mean	43	41	34	44
		SD	34	25	12	30
		N	10	10	10	10
		%Diff		-3.7	-20.0	3.5

General Footnote [Statistical Test: Anova and Dunnett's test Transformation: Automatic]

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

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**Appendix A**  
**Individual Animal Clinical Pathology Data**

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

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INDIVIDUAL ANIMAL CLINICAL PATHOLOGY DATA

EXPLANATORY NOTES

ABBREVIATIONS:

General:

- - not observed  
. - not taken, not performed, not observed, or results not valid  
Man - many  
Mod - moderate  
NPH - not performed due to hemolysis  
OK - sample condition OK for testing  
ppm - parts per million  
QNS - sample quantity not sufficient for testing

Individual Hematology Values:

WB - whole blood condition  
RBC - red blood cell count  
HGB - hemoglobin  
HCT - hematocrit  
MCV - mean corpuscular (cell) volume  
MCH - mean corpuscular (cell) hemoglobin  
MCHC - mean corpuscular (cell) hemoglobin concentration  
RDW - red cell distribution width  
PLT - platelet count  
WBC - white blood cell count  
ANEU - absolute neutrophil (all forms)  
ALYM - absolute lymphocyte  
AMON - absolute monocyte  
AEOS - absolute eosinophil  
ABAS - absolute basophil  
ALUC - absolute large unstained cell  
ARET - absolute reticulocyte

Individual Coagulation Values:

PHEM - plasma hemolysis  
PLIP - plasma lipemia  
PICT - plasma icterus  
PT - prothrombin time  
APTT - activated partial thromboplastin time

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

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INDIVIDUAL ANIMAL CLINICAL PATHOLOGY DATA

EXPLANATORY NOTES (Continued)

ABBREVIATIONS: (Continued)

Individual Clinical Chemistry Values:

HEM - hemolysis  
LIP - lipemia  
ICT - icterus  
AST - aspartate aminotransferase  
ALT - alanine aminotransferase  
SDH - sorbitol dehydrogenase  
ALKP - alkaline phosphatase  
BILI - total bilirubin  
BUN - urea nitrogen  
CREA - creatinine  
CHOL - cholesterol  
TRIG - triglycerides  
GLUC - glucose  
TP - total protein  
ALB - albumin  
GLOB - globulin  
CALC - calcium  
IPHS - inorganic phosphorous  
NA - sodium  
K - potassium  
CL - chloride

Individual Urinalysis Values:

QUAL - quality (modifies color)  
COL - color  
CLAR - clarity  
UVOL - volume  
pH - the logarithm of the reciprocal of the hydrogen ion concentration  
SG - specific gravity  
UGLC - Glucose  
KET - ketone  
UBIL - bilirubin  
BLD - blood  
URO - urobilinogen  
UMTP - protein

Individual Urine Microscopic Examination Values:

EPIT - epithelial cells  
UWBC - urine white blood cells  
URBC - urine red blood cells  
NCRY - normal crystals  
MICR - microorganisms  
SPER - sperm  
REPI - renal epithelial cell  
MUC - mucus strand

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

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INDIVIDUAL ANIMAL CLINICAL PATHOLOGY DATA

EXPLANATORY NOTES (Continued)

NOTES:

When individual animal data are not reported, it may be due to one of the following reasons or other reasons:

the sample was clotted (CLOT)  
there was insufficient sample for testing (QNS)  
a valid result could not be obtained (NRV)  
the sample was not suitable for testing  
the animal died prior to sample collection  
no sample was available for testing (NSR)

Only positive findings were recorded for special observations (e.g., additional cell types) or observations marked other.

Clinical Pathology Results for  
Soy Lecithin/Lehlin Preparation: A 28-Day Dietary Study in Rats

Continuation of Analysis: Clinical Pathology Data

Sex: Male Days Relative to Start Date

n mg/kg/day Group 1	CBC/DIFF/BLETH/ChemU						
	WB	RBC <sup>a</sup>	HGB <sup>b</sup>	HCT <sup>c</sup>	MCV <sup>d</sup>	MCH <sup>e</sup>	MCHC <sup>f</sup>
		(x10 <sup>6</sup> /µL)	(g/dL)	(%)	(fL)	(pg)	(g/dL)
	22	22	22	22	22	22	22
7001	OK	7.48	15.5	44.6	59.6	20.8	34.9
7002	OK	7.66	15.2	44.5	57.9	19.8	34.2
7003	OK	7.65	15.5	43.1	58.9	20.3	34.5
7004	OK	8.10	16.1	47.5	58.7	19.9	33.9
7005	OK	7.06	15.5	45.0	58.6	20.1	34.3
7006	OK	7.37	15.4	45.0	61.0	21.9	34.3
7007	OK	7.55	15.4	45.1	59.7	20.5	34.2
7008	OK	7.95	15.6	45.6	57.4	19.6	34.1
7009	OK	7.79	16.2	43.8	58.8	20.8	35.3
7010	OK	7.96	16.0	46.5	58.4	20.6	34.3

Sex: Male Days Relative to Start Date

n mg/kg/day Group 1	CBC/DIFF/BLETH/ChemU						
	RDW	PLT <sup>g</sup>	WBC <sup>h</sup>	ANFI <sup>i</sup>	ALTM <sup>j</sup>	ASp-N <sup>k</sup>	ASp-O <sup>l</sup>
	(%)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)
	22	22	22	22	22	22	22
7001	12.0	1128	15.34	2.23	12.17	0.31	0.11
7002	11.7	1118	15.88	1.52	9.71	0.31	0.22
7003	11.9	1217	10.89	1.20	9.30	0.16	0.08
7004	12.2	1078	13.86	3.17	10.49	0.29	0.17
7005	12.8	1259	14.23	1.34	12.39	0.18	0.07
7006	12.1	960	13.77	1.69	10.55	0.50	0.15
7007	12.0	1076	12.21	1.35	10.01	0.35	0.15
7008	12.2	1142	15.54	1.95	11.68	0.22	0.09
7009	12.0	1240	11.73	1.51	9.48	0.39	0.14
7010	12.3	1346	13.00	2.92	9.48	0.36	0.13

Group 1: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 2: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 3: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Clinical Pathology Results for  
Soy Lecithin Preparation: A 28-Day Dietary Study in Rats

Individual Values - Clinical Pathology Data

Sex: Male Days Relative to Start Date:

Dose mg/kg/day Group 1	ADAS	ALBT	ALBT
	(x10 <sup>3</sup> µg/L)	(x10 <sup>3</sup> µg/L)	(x10 <sup>3</sup> µg/L)
	22	22	22
7001	0.11	0.11	241.2
7002	0.06	0.06	255.6
7003	0.07	0.08	213.2
7004	0.06	0.06	233.5
7005	0.13	0.13	205.6
7006	0.04	0.13	268.3
7007	0.10	0.07	233.9
7008	0.14	0.07	197.9
7009	0.12	0.06	199.8
7010	0.10	0.04	226.2

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.



Chemical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

Chemical Pathology: Hematology (Hematology)

Sex: Male Days: Relative to Start Date

SID mg/kg/day Group 2	CBC DIFF RETIC Count <sup>1</sup>						
	WB	RBC	HGB	HCT	MCV	MCH	MCHC
		(x10 <sup>6</sup> /µL)	(g/dL)	(%)	(fL)	(pg)	(g/dL)
	22	22	22	22	22	22	22
7021	OK	7.67	16.6	47.6	62.0	21.6	34.8
7022	OK	8.13	15.1	43.1	53.1	18.6	33.6
7023	OK	7.4	15.3	44.3	59.5	19.8	33.0
7024	OK	7.28	14.7	42.8	58.8	20.2	34.4
7025	OK	7.16	14.9	43.7	62.0	20.1	34.0
7026	OK	7.16	14.9	43.3	61.1	21.0	34.3
7027	OK	8.06	15.7	46.2	57.1	19.5	33.9
7028	OK	7.74	15.5	44.7	57.7	20.0	34.7
7029	OK	7.52	15.7	43.9	61.0	20.9	34.3
7030	OK	7.31	15.7	46.0	62.6	21.1	34.2

Sex: Male Days: Relative to Start Date

SID mg/kg/day Group 2	CBC DIFF RETIC Count <sup>1</sup>						
	RDW	PLT	WBC <sup>2</sup>	ANFI <sup>3</sup>	ALTSI <sup>4</sup>	ASIS <sup>5</sup>	ASIS <sup>5</sup>
	(%)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)
	22	22	22	22	22	22	22
7021	12.7	1315	1340	1.55	11.99	0.28	0.10
7022	12.9	1136	16.79	2.38	13.33	0.44	0.35
7023	13.0	1217	11.65	1.13	10.68	0.27	0.07
7024	12.1	1263	13.53	1.76	11.28	0.26	0.11
7025	13.7	1195	12.75	2.50	9.71	0.28	0.08
7026	12.7	1172	13.87	1.79	11.60	0.24	0.10
7027	11.7	1358	11.49	2.09	8.76	0.54	0.10
7028	12.3	1109	21.87	2.16	1.81	0.23	0.12
7029	12.1	1220	14.96	2.26	11.96	0.45	0.13
7030	12.1	1185	14.36	2.34	11.34	0.40	0.11

<sup>1</sup>Group 2: SID mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
<sup>2</sup>Group 1: 1025 mg/kg/day of test substance corresponds to 50 mg/kg/day of the active ingredient  
<sup>3</sup>Group 1: 1330 mg/kg/day of test substance corresponds to 70 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Sex-Linked Hemoglobin Preparation: A 28-Day Dietary Study in Rats

Continuation of Tables 1 through 4 of Study 2014

Sex: Male; Days: Relative to Start Date

512 mg/kg/day Group 2	AHAS	ALU <sup>a</sup>	AREI
	(x10 <sup>3</sup> µL)	(x10 <sup>3</sup> µL)	(x10 <sup>3</sup> µL)
	22	22	22
7021	0.13	0.06	282.3
7022	0.13	0.13	224.6
7023	0.07	0.05	197.6
7024	0.07	0.03	225.0
7025	0.08	0.06	265.7
7026	0.08	0.07	220.8
7027	0.05	0.06	230.8
7028	0.14	0.08	167.0
7029	0.04	0.10	234.0
7030	0.07	0.09	308.3

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Lectin/albumin Preparation: A 28-Day Dietary Study in Rats

Continuation of Results: Hematology (continued)

Sex, Age, Weight (Group)	Days Relative to Start Date						
	CBC-DIFF-BLEED Comp A						
	WB	RBC*	HGB	HCT	MCV	MPV	ABPC*
	(x10 <sup>6</sup> /µL)	(g/dL)	(%)	(fL)	(pg)		(g/dL)
	22	22	22	22	22	22	22
7041	OK	7.74	15.2	44.6	57.6	19.6	34.1
7042	OK	7.44	16.1	46.8	60.2	20.8	34.5
7043	OK	7.76	15.4	45.3	58.4	19.9	34.1
7044	OK	7.72	15.9	46.7	60.5	21.6	34.1
7045	OK	7.87	16.1	46.2	58.1	21.1	34.8
7046	OK	6.75	14.1	40.7	59.9	20.8	34.8
7047	OK	7.45	15.5	45.5	61.1	21.8	34.1
7048	OK	7.25	15.2	44.4	61.2	21.0	34.3
7049	OK	7.91	15.7	45.0	58.9	19.8	34.8
7050	OK	7.81	15.7	45.9	58.9	20.2	34.2

Sex, Age, Weight (Group)	Days Relative to Start Date						
	CBC-DIFF-BLEED Comp B						
	RBC	PLT	WBC*	ASPL	ALPL	ALN	ALOS
(%)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)
	22	22	22	22	22	22	22
7041	12.1	126	11.55	1.64	9.45	0.25	0.08
7042	12.5	116.5	14.92	2.17	12.20	0.28	0.16
7043	12.3	125.8	12.44	2.31	9.52	0.37	0.15
7044	13.0	133	10.33	1.87	7.86	0.26	0.12
7045	12.1	169.5	9.46	1.34	7.63	0.27	0.11
7046	12.5	139	11.47	1.89	9.91	0.32	0.19
7047	12.6	118.9	10.04	1.58	7.95	0.31	0.10
7048	12.6	132	12.44	1.68	10.98	0.25	0.05
7049	12.9	112.1	8.79	1.03	7.41	0.22	0.07
7050	12.6	169	9.86	2.12	7.29	0.23	0.13

\*Group 2: 312 mg/kg/day of test substance corresponds to 290 mg/kg/day of the active ingredient.  
 \*Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
 \*Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Clinical Pathology Results for  
Sex: Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

Continuation of Tables 1 and 2 from Table 1001

Sex: Male Days Relative to Start Date

1024 mg/kg/day Group 3	ADMS	ALU*	AREF
	(x10 <sup>3</sup> /pl.)	(x10 <sup>3</sup> /pl.)	(x10 <sup>3</sup> /pl.)
	22	22	22
7041	0.05	0.08	270.7
7042	0.09	0.10	228.3
7043	0.06	0.06	293.3
7044	0.06	0.04	235.3
7045	0.08	0.05	222.1
7046	0.07	0.08	263.6
7047	0.07	0.05	243.9
7048	0.06	0.05	245.0
7049	0.09	0.04	211.8
7050	0.04	0.04	244.2

Group 2: 512 mg/kg/day of test substance corresponds to 256 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 512 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 768 mg/kg/day of the active ingredient.

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

INDIVIDUAL ANIMAL CLINICAL PATHOLOGY DATA

Sex: Male Days(s) Relative to Start Date:

TAN- mg/kg/day Group 4	CBC/DIFF/BETIC Count						
	WB	RBC	HGB	HCT	MCV	MCH	MCHC
		(x10 <sup>6</sup> /µL)	(g/dL)	(%)	(fL)	(pg)	(g/dL)
	22	22	22	22	22	22	22
7061	OK	8.23	15.9	46.6	56.6	19.3	34.1
7062	OK	7.77	15.8	45.4	58.5	20.4	34.9
7063	OK	7.59	15.9	45.5	59.9	21.0	35.0
7064	OK	7.36	16.1	47.1	63.9	21.8	34.2
7065	OK	7.84	16.2	46.4	59.2	20.6	34.8
7066	OK	7.40	14.0	44.8	60.5	20.2	33.3
7067	OK	7.64	15.9	45.5	59.6	20.8	34.9
7068	OK	7.62	15.7	45.1	59.2	20.5	34.7
7069	OK	8.06	16.1	46.9	58.6	20.1	34.4
7070	OK	7.58	16.1	45.9	60.5	21.2	35.0

Sex: Male Days(s) Relative to Start Date:

TAN- mg/kg/day Group 4	CBC/DIFF/BETIC Count						
	WB	RBC	HGB	HCT	MCV	MCH	MCHC
		(x10 <sup>6</sup> /µL)	(g/dL)	(%)	(fL)	(pg)	(g/dL)
	22	22	22	22	22	22	22
7061	OK	8.23	15.9	46.6	56.6	19.3	34.1
7062	OK	7.77	15.8	45.4	58.5	20.4	34.9
7063	OK	7.59	15.9	45.5	59.9	21.0	35.0
7064	OK	7.36	16.1	47.1	63.9	21.8	34.2
7065	OK	7.84	16.2	46.4	59.2	20.6	34.8
7066	OK	7.40	14.0	44.8	60.5	20.2	33.3
7067	OK	7.64	15.9	45.5	59.6	20.8	34.9
7068	OK	7.62	15.7	45.1	59.2	20.5	34.7
7069	OK	8.06	16.1	46.9	58.6	20.1	34.4
7070	OK	7.58	16.1	45.9	60.5	21.2	35.0

Group 1: 212 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
 Group 2: 1025 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
 Group 3: 1535 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Lecthemoglobin Preparation: A 28-Day Dietary Study in Rats

Individual Animal Clinical Pathology Data

Sex: Male Days: Relative to Start Date

USN mg/kg/day Group 4	ABAS	ALP*	ARET
	(x10 <sup>3</sup> U/L)	(x10 <sup>3</sup> U/L)	(x10 <sup>3</sup> U/L)
	22	22	22
7061	0.06	0.06	288.8
7062	0.09	0.04	288.4
7063	0.21	0.09	319.0
7064	0.10	0.10	319.0
7065	0.12	0.06	242.2
7066	0.05	0.07	224.8
7067	0.06	0.14	299.9
7068	0.17	0.15	194.5
7069	0.05	0.04	235.2
7070	0.05	0.06	214.2

Group 2: 512 mg/kg/day of test substance corresponds to 256 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 512 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 768 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

CLINICAL PATHOLOGY RESULTS - CLINICAL PATHOLOGY TESTS

Sex: Female Days Relative to Start Date

n mg/kg/day Group 1	CBC/DIFF/RET/PLT Count						
	WB	RBC	HGB	HCT	MCV	MPV	MCHC
	(%)	(x10 <sup>6</sup> /µL)	(g/dL)	(%)	(fL)	(pg)	(g/dL)
	22	22	22	22	22	22	22
7011	OK	7.71	15.7	43.5	56.4	20.4	36.1
7012	OK	7.82	15.7	44.8	57.2	20.1	35.2
7013	OK	7.22	14.8	42.4	58.8	20.5	34.9
7014	OK	7.72	15.6	44.4	57.5	20.2	35.1
7015	OK	7.33	15.9	43.3	59.2	20.3	34.7
7016	OK	7.41	14.6	42.3	57.3	19.7	34.4
7017	OK	7.94	16.1	44.5	56.1	20.4	36.3
7018	OK	7.76	15.6	45.5	58.6	20.1	34.5
7019	OK	7.67	15.4	43.5	56.7	20.1	35.5
7020	OK	7.33	14.7	41.6	56.7	20.6	35.3

Sex: Female Days Relative to Start Date

n mg/kg/day Group 1	CBC/DIFF/RET/PLT Count						
	RDW	PLT	WBC	ANEM	ALYM	ASER	ABOS
	(%)	(x10 <sup>9</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)
	22	22	22	22	22	22	22
7011	11.2	1.38	9.69	1.42	7.94	0.16	0.08
7012	10.9	1.73	8.81	1.49	6.96	0.21	0.10
7013	11.1	1.282	9.63	1.65	7.43	0.36	0.17
7014	11.2	1.684	10.65	1.55	8.92	0.14	0.10
7015	11.2	1.217	8.53	2.00	6.24	0.13	0.09
7016	11.6	1.126	11.48	1.89	9.02	0.40	0.17
7017	10.8	1.123	8.94	0.87	7.73	0.13	0.13
7018	12.3	1.604	11.97	1.28	10.14	0.19	0.13
7019	11.1	1.371	13.21	1.48	10.90	0.58	0.09
7020	11.5	1.269	7.89	1.33	6.20	0.21	0.10

Group 1: 112 mg/kg/day of test substance corresponds to 280 mg/kg/day of the active ingredient  
 Group 2: 1028 mg/kg/day of test substance corresponds to 280 mg/kg/day of the active ingredient  
 Group 3: 1530 mg/kg/day of test substance corresponds to 280 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy-Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

Investigator: ARIANA LINDA LAM, DVM, PhD

Sex: Female Days Relative to Start Date

ID mg/kg/day Group 1	ADAS	MCV*	ARET
	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)
	22	22	22
7011	0.05	0.03	151.8
7012	0.02	0.04	192.8
7013	0.02	0.06	205.3
7014	0.04	0.09	215.0
7015	0.03	0.03	243.8
7016	0.03	0.05	153.5
7017	0.03	0.04	226.8
7018	0.05	0.07	252.5
7019	0.03	0.06	194.2
7020	0.02	0.04	222.0

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1624 mg/kg/day of test substance corresponds to 800 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient



Clinical Pathology Results for  
Sex: Leghämoglobin Preparation: A 28-Day Dietary Study in Rats

Chemical Analysis: Hematology (H) (U)

Sex: Female Days Relative to Start Date

SID mg/kg/day Group 2	CBC/DIFF/BETHC Count						
	WB	RBC	HGB	HCT	MCV	MCH	MCHC
		(x10 <sup>6</sup> /µL)	(g/dL)	(%)	(fL)	(pg)	(g/dL)
	22	22	22	22	22	22	22
7031	OK	8.35	16.2	43.4	54.4	19.4	35.6
7032	OK	8.12	16.9	47.4	56.3	20.6	35.6
7033	OK	8.13	15.5	44.5	54.8	19.1	34.8
7034	OK	7.89	16.1	46.0	58.3	20.4	34.9
7035	OK	7.36	15.1	44.5	61.0	21.5	35.3
7036	OK	7.93	16.5	46.3	58.4	20.8	35.5
7037	OK	8.48	16.5	46.4	54.8	19.5	35.6
7038	OK	7.80	16.2	46.1	57.2	20.7	35.1
7039	OK	8.21	16.7	47.7	58.1	20.4	35.1
7040	OK	7.63	15.7	44.4	58.2	20.5	35.3

Sex: Female Days Relative to Start Date

SID mg/kg/day Group 2	CBC/DIFF/BETHC Count						
	RDW	PLT	WBC	ANCU	ALYMI	ANUS	ANOR
	(%)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)
	22	22	22	22	22	22	22
7031	11.3	1967	11.91	0.92	10.44	0.32	0.13
7032	11.8	1387	10.43	0.99	9.05	0.19	0.08
7033	11.1	1199	10.60	2.26	13.15	0.32	0.10
7034	10.3	1132	9.70	1.45	7.97	0.21	0.09
7035	11.3	1368	12.45	2.38	9.47	0.37	0.09
7036	11.4	1276	11.46	1.99	8.89	0.36	0.19
7037	10.8	1197	12.98	1.79	10.55	0.26	0.17
7038	11.9	1975	10.91	0.73	9.50	0.32	0.16
7039	11.2	1648	10.62	1.20	8.78	0.34	0.17
7040	11.8	1696	12.10	1.84	9.70	0.34	0.17

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 1: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 0: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Clinical Pathology Results for  
Soy Lectin Hemagglutinin Preparation: A 28-Day Dietary Study in Rats

Continued from Clinical Pathology Data

Sex: Female mg/kg/day Group 2	Days Relative to Start Date		
	ABAS	ALU <sup>a</sup>	ARET
	(x10 <sup>3</sup> )/pL	(x10 <sup>3</sup> )/pL	(x10 <sup>3</sup> )/pL
	22	22	22
7031	0.07	0.06	155.8
7032	0.04	0.06	199.4
7033	0.10	0.10	205.1
7034	0.03	0.05	163.2
7035	0.06	0.06	214.8
7036	0.06	0.07	222.9
7037	0.09	0.09	133.1
7038	0.17	0.07	137.0
7039	0.07	0.05	181.7
7040	0.07	0.07	200.3

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 1: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Sex: Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

UNCLINICAL ANALYSIS - 10/20/04 10:14:57 AM

Sex: Female Days Relative to Start Date

1021 mg/kg/day Group 3	CBC/DIFF/RETIC (Cont'd)						
	WB	RBC	HGB	HCT	MCV	MCH	MCHC
		(x10 <sup>6</sup> /µL)	(g/dL)	(%)	(fL)	(pg)	(g/dL)
	22	22	22	22	22	22	22
7051	OK	7.50	15.3	42.6	56.8	20.5	36.0
7052	OK	7.61	15.7	44.1	58.0	20.6	35.5
7053	OK	7.91	15.6	44.7	56.5	19.8	33.9
7054	OK	8.16	15.9	46.3	58.8	19.5	34.0
7055	OK	7.87	15.2	43.2	55.0	19.4	35.3
7056	OK	7.91	15.7	45.0	56.9	19.8	34.8
7057	OK	7.64	15.4	43.6	57.0	20.2	35.4
7058	OK	8.02	15.7	44.5	55.4	19.5	35.3
7059	OK	7.73	16.1	45.9	59.1	20.8	35.1
7060	OK	8.26	16.3	46.6	56.4	19.9	35.5

Sex: Female Days Relative to Start Date

1021 mg/kg/day Group 3	CBC/DIFF/RETIC (Cont'd)						
	HDW	PLT	WBC	ASPT	ALYM	ASSTN	AROS
	(%)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)
	22	22	22	22	22	22	22
7051	11.2	1289	5.91	146	6.0	0.27	0.13
7052	11.2	1253	8.44	137	6.68	0.20	0.15
7053	11.9	1200	12.97	2.97	9.03	0.66	0.19
7054	11.3	1060	11.78	2.33	8.94	0.32	0.06
7055	11.1	1334	8.29	1.23	6.65	0.25	0.08
7056	11.5	1362	15.10	7.02	12.16	0.50	0.23
7057	11.2	1178	12.42	0.88	11.03	0.21	0.15
7058	11.0	1305	17.73	3.07	13.88	0.47	0.18
7059	11.0	1640	13.10	0.89	11.46	0.38	0.20
7060	10.9	1383	8.10	1.07	6.50	0.15	0.15

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
 Group 3: 1025 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
 Group 4: 1539 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

Continuation of Table 1 Clinical Pathology Data

Sex: Female mg/kg/day Group 3	Days Relative to Start Date		
	ADAS	ALUT	ARET
	(x10 <sup>3</sup> / $\mu$ L)	(x10 <sup>3</sup> / $\mu$ L)	(x10 <sup>3</sup> / $\mu$ L)
	22	32	22
7051	0.03	0.03	38.9
7052	0.02	0.03	187.5
7053	0.06	0.05	170.5
7054	0.05	0.08	160.2
7055	0.05	0.03	169.8
7056	0.11	0.11	158.7
7057	0.07	0.07	203.0
7058	0.12	0.11	164.4
7059	0.05	0.10	173.4
7060	0.03	0.04	174.5

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Lecithin/Inulin Preparation: A 28-Day Dietary Study in Rats

Continuation of Analysis: Clinical Pathology Data

Sex: Female Days(s) Relative to Start Date

Dose mg/kg/day (Group 4)	CBC DIFF RETIC Count						
	WB	RBC	HGB	HCT	MCV	MCH	MCHC
		(x10 <sup>6</sup> /µL)	(g/dL)	(%)	(fL)	(pg)	(g/dL)
	22	22	22	22	22	22	22
7071	OK	7.57	14.7	42.2	55.7	19.4	34.9
7072	OK	7.51	14.1	41.3	56.4	19.7	34.8
7073	OK	7.32	15.4	44.8	61.2	21.0	34.4
7074	OK	7.43	15.0	42.3	56.8	20.2	35.0
7075	OK	7.95	15.6	41.0	55.4	19.9	35.5
7076	OK	7.27	15.7	43.9	60.4	21.0	35.8
7077	OK	8.12	16.7	47.1	58.0	20.6	35.5
7078	OK	7.67	16.0	46.2	60.2	20.8	34.6
7079	OK	7.82	15.2	43.1	55.1	19.4	35.3
7080	OK	7.31	14.9	42.9	57.5	20.3	35.4

Sex: Female Days(s) Relative to Start Date

Dose mg/kg/day (Group 4)	CBC DIFF RETIC Count						
	RDW	PLT	WBC	ANEU	ALYMI	ANLN	ABKX
	(%)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)	(x10 <sup>3</sup> /µL)
	22	22	22	22	22	22	22
7071	12.4	1062	12.22	3.08	8.75	0.28	0.11
7072	11.0	1262	7.00	0.79	5.91	0.13	0.12
7073	11.3	1341	17.13	4.48	12.09	0.55	0.15
7074	11.6	1235	5.39	1.19	1.01	0.60	0.03
7075	11.0	1366	10.77	1.08	9.28	0.19	0.09
7076	10.9	1390	10.86	1.32	9.35	0.20	0.10
7077	11.7	1193	10.58	1.21	8.64	0.43	0.26
7078	10.9	1298	14.13	0.92	12.00	0.21	0.17
7079	11.9	1153	7.79	0.79	6.73	0.15	0.06
7080	12.0	1052	6.06	1.20	4.65	0.67	0.10

Group 2: 312 mg/kg/day of test substance corresponds to 280 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1500 mg/kg/day of test substance corresponds to 700 mg/kg/day of the active ingredient.

Clinical Pathology Results for  
Soy Lecithin/lecithin Preparation: A 28-Day Dietary Study in Rats

Continuation of Tables 1 through 10 of the CLP Report

Sex: female Days Relative to Start Date

1536 mg/kg/day Group 4	ALB	ALU <sup>a</sup>	ARE <sup>b</sup>
	(x10 <sup>3</sup> g/L)	(x10 <sup>3</sup> g/L)	(x10 <sup>3</sup> g/L)
	22	22	22
7071	0.05	0.04	230.7
7072	0.02	0.01	179.2
7073	0.14	0.14	214.5
7074	0.01	0.03	164.1
7075	0.05	0.06	132.9
7076	0.05	0.04	176.2
7077	0.06	0.06	169.7
7078	0.10	0.10	155.2
7079	0.03	0.04	189.5
7080	0.02	0.02	228.7

Group 2: 512 mg/kg/day of test substance corresponds to 256 mg/kg/day of the active ingredient  
 Group 3: 1024 mg/kg/day of test substance corresponds to 512 mg/kg/day of the active ingredient  
 Group 4: 1536 mg/kg/day of test substance corresponds to 768 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Lecithin Preparation: A 28-Day Dietary Study in Rats

TABLE 10. Clinical Pathology (Continued)

ID mg/kg/day Group 1	Sex: Male Days Relative to Start Date				
	PHEM	PLIP	PCT	PT (sec)	APTT (sec)
	29	29	29	29	29
7001	None	None	None	11.1	20.5
7002	None	None	None	10.6	18.6
7003	None	None	None	10.3	20.5
7004	None	None	None	10.6	25.4
7005	None	None	None	10.5	17.7
7006	None	None	None	10.1	22.3
7007	None	None	None	11.1	17.5
7008	None	None	None	10.9	20.2
7009	None	None	None	10.8	19.8
7010	None	None	None	10.6	19.1

ID mg/kg/day Group 2	Sex: Male Days Relative to Start Date				
	PHEM	PLIP	PCT	PT (sec)	APTT (sec)
	29	29	29	29	29
7021	None	None	None	11.1	21.7
7022	None	None	None	10.6	31.6
7023	None	None	None	10.7	26.1
7024	None	None	None	10.4	19.7
7025	None	None	None	10.8	31.0
7026	None	None	None	10.7	21.5
7027	None	None	None	10.5	21.2
7028	None	None	None	11.3	22.6
7029	None	None	None	10.7	22.4
7030	None	None	None	10.0	17.5

Group 1: 112 mg/kg/day of test substance corresponds to 29 mg/kg/day of the active ingredient  
 Group 2: 1024 mg/kg/day of test substance corresponds to 256 mg/kg/day of the active ingredient  
 Group 3: 1536 mg/kg/day of test substance corresponds to 384 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Lecithin Preparation: A 28-Day Dietary Study in Rats

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Sex: Male Days(s) Relative to Start Date

1024 mg/kg/day Group 3	PFEM	PLIP	PIC1	PT	APTT
				(sec)	(sec)
	29	29	29	29	29
7041	None	None	None	10.3	41.9
7042	None	None	None	10.9	27.8
7043	None	None	None	10.3	21.9
7044	None	None	None	10.7	23.0
7045	None	None	None	10.9	21.1
7046	None	None	None	10.4	22.4
7047	None	None	None	10.1	17.0
7048	None	None	None	10.7	19.9
7049	None	None	None	10.6	20.8
7050	None	None	None	10.9	26.0

Sex: Male Days(s) Relative to Start Date

1536 mg/kg/day Group 4	PFEM	PLIP	PIC1	PT	APTT
				(sec)	(sec)
	29	29	29	29	29
7061	None	None	None	10.7	35.2
7062	None	None	None	10.7	28.0
7063	None	None	None	10.5	25.2
7064	None	None	None	10.1	23.0
7065	None	None	None	10.6	20.8
7066	None	None	None	10.2	21.8
7067	None	None	None	10.3	17.8
7068	None	None	None	10.3	20.9
7069	None	None	None	10.9	22.6
7070	None	None	None	10.7	23.3

Group 2: 517 mg/kg/day of test substance corresponds to 290 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 580 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 860 mg/kg/day of the active ingredient



Clinical Pathology Results for  
Sex: Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

INDIVIDUAL ANIMAL TESTS BY TREATMENT GROUP

Sex: Female Digits Relative to Start Date

01 mg/kg/day Group 1	PHEM	PLP	PLT	PT	APTT
				(sec)	(sec)
	31	30	30	30	30
7011	None	None	None	9.8	22.6
7012	None	None	None	10.4	23.4
7013	None	None	None	10.0	18.6
7014	None	None	None	10.1	21.2
7015	None	None	None	10.0	23.8
7016	None	None	None	10.1	26.8
7017	None	None	None	9.9	19.6
7018	None	None	None	10.1	22.6
7019	None	None	None	9.8	19.2
7020	None	None	None	10.2	21.3

Sex: Female Digits Relative to Start Date

512 mg/kg/day Group 2	PHEM	PLP	PLT	PT	APTT
				(sec)	(sec)
	31	30	30	30	30
7001	None	None	None	10.0	17.3
7002	None	None	None	9.7	27.4
7003	None	None	None	9.9	16.3
7004	None	None	None	9.9	20.0
7005	None	None	None	8.5	18.1
7006	None	None	None	10.0	21.4
7007	None	None	None	9.6	19.4
7008	None	None	None	10.1	18.6
7009	None	None	None	9.6	19.0
7010	None	None	None	10.1	22.1

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Lectin/albumin Preparation: A 28-Day Dietary Study in Rats

INDIVIDUAL ANIMAL CLINICAL PATHOLOGY DATA

Sex: Female Days Relative to Start Date

1024 mg/kg/day Group 3	PHEM	PLP	PBT	PT	APTT
				(sec)	(sec)
	91	10	90	90	90
7001	None	None	None	10.6	29.1
7002	None	None	None	10.1	27.3
7003	None	None	None	9.8	14.9
7004	None	None	None	9.4	13.1
7005	None	None	None	10.0	23.3
7006	None	None	None	10.1	21.0
7007	None	None	None	9.9	23.8
7008	None	None	None	9.7	15.4
7009	None	None	None	10.2	32.4
7010	None	None	None	10.0	17.2

Sex: Female Days Relative to Start Date

1500 mg/kg/day Group 4	PHEM	PLP	PBT	PT	APTT
				(sec)	(sec)
	91	10	90	90	90
7001	None	None	None	9.7	18.2
7002	None	None	None	9.9	20.3
7003	None	None	None	9.4	17.6
7004	None	None	None	10.0	16.9
7005	None	None	None	9.7	18.3
7006	None	None	None	10.1	23.6
7007	None	None	None	9.7	20.1
7008	None	None	None	10.0	20.3
7009	None	None	None	9.9	18.8
7010	None	None	None	9.9	19.8

Group 2: 512 mg/kg/day of test substance corresponds to 256 mg/kg/day of the active ingredient  
 Group 3: 1024 mg/kg/day of test substance corresponds to 512 mg/kg/day of the active ingredient  
 Group 4: 1536 mg/kg/day of test substance corresponds to 768 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Lecithin/Inulin Preparation: A 28-Day Dietary Study in Rats

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Sex: Male Days(s) Relative to Start Date

ID mg/kg/dose Group 1	Chemical Parameters						
	HEM	LOP	ICT	AST (U/L)	ALT (U/L)	SGOT (U/L)	ALKP (U/L)
	22	22	22	22	22	22	22
7001	Trace	None	None	NPH	25	NPH	184
7002	Trace	None	None	NPH	25	NPH	162
7003	Trace	None	None	NPH	28	NPH	166
7004	None	None	None	22	26	10.3	241
7005	None	None	None	8	29	7	202
7006	Trace	None	None	NPH	29	NPH	181
7007	None	None	None	22	29	7.9	173
7008	Trace	None	None	NPH	28	NPH	186
7009	None	None	None	20	25	8.4	158
7010	None	None	None	65	26	6.6	172

Sex: Male Days(s) Relative to Start Date

ID mg/kg/dose Group 1	Chemical Parameters						
	BILI (mg/dL)	BUN (mg/dL)	CREA (mg/dL)	TRIG C30 L (mg/dL)	TRIG S (mg/dL)	TRIG M (mg/dL)	TP (g/dL)
	22	22	22	22	22	22	22
7001	0.19	12	0.23	38	54	113	6.1
7002	0.18	11	0.23	106	82	82	6.6
7003	0.19	9	0.20	84	97	88	5.9
7004	0.16	12	0.24	73	80	87	6.2
7005	0.17	11	0.23	73	80	89	6.0
7006	0.20	10	0.23	89	80	120	6.0
7007	0.14	9	0.20	15	55	92	5.6
7008	0.17	8	0.22	68	72	81	6.0
7009	0.15	11	0.20	74	80	96	6.4
7010	0.14	11	0.22	69	62	93	5.9

Group 1: 312 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 2: 1024 mg/kg/day of test substance corresponds to 800 mg/kg/day of the active ingredient  
Group 3: 1536 mg/kg/day of test substance corresponds to 1200 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leptogemoglobin Preparation - A 28-Day Dietary Study in Rats

CLINICAL PATHOLOGY RESULTS - CLINICAL CHEMISTRY DATA

Sex: Male Days(s) Relative to Start Date

ID mg/kg/day Group 1	Chemistry Chem Pks						
	ALB	GLU	CAC	BUN	NA	K	CL
	(g/dL)	(g/dL)	(mg/dL)	(mg/dL)	(mmol/L)	(mmol/L)	(mmol/L)
	32	32	32	32	32	32	32
7061	3.2	2.9	10.7	SPH	143.7	4.91	102.5
7062	3.1	2.9	10.3	SPH	141.6	5.37	101.5
7063	3.1	2.8	10.5	SPH	140.9	5.02	100.8
7064	3.1	3.1	10.4	8.6	142.0	4.96	101.5
7065	3.2	2.8	10.2	9.0	142.5	4.95	101.1
7066	3.1	2.9	10.5	SPH	140.8	5.32	101.8
7067	3.0	2.6	10.0	8.1	138.9	4.91	94.0
7068	3.2	2.8	10.3	SPH	141.9	4.65	102.2
7069	3.3	3.1	10.8	8.3	141.4	5.29	101.1
7070	3.1	2.8	10.4	8.9	141.5	4.82	101.4

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Lecithin Preparation - A 28-Day Dietary Study in Rats

UNIVERSITY MICROFILMS INTERNATIONAL

Sex: Male Days Relative to Start Date

512 mg/kg/day Group 2	Olivencia Chem Plus						
	HEM	LEP	UCT	AST	ALT	SEB	ALKP
	(mg/dL)	(mg/dL)	(mg/dL)	(U/L)	(U/L)	(U/L)	(U/L)
	22	22	22	22	22	22	22
7021	None	None	None	76	30	80	182
7022	None	None	None	85	25	19	245
7023	None	None	None	NPH	26	NPH	218
7024	None	None	None	76	24	76	184
7025	None	None	None	82	29	117	182
7026	None	None	None	74	21	74	204
7027	None	None	None	81	35	84	264
7028	None	None	None	68	24	78	208
7029	None	None	None	63	27	91	196
7030	None	None	None	92	33	82	237

Sex: Male Days Relative to Start Date

512 mg/kg/day Group 2	Olivencia Chem Plus						
	BILI	BUN	CREA	CEAC	TRIG	GLUC	TP
	(mg/dL)	(mg/dL)	(mg/dL)	(mg/dL)	(mg/dL)	(mg/dL)	(g/dL)
	22	22	22	22	22	22	22
7021	0.17	11	0.24	86	73	186	8.2
7022	0.20	11	0.20	72	77	89	5.7
7023	0.17	9	0.25	97	65	114	8.4
7024	0.18	14	0.24	51	39	190	6.1
7025	0.18	11	0.24	53	65	36	6.6
7026	0.15	12	0.20	118	60	90	5.9
7027	0.15	12	0.23	55	61	108	6.0
7028	0.15	9	0.23	29	92	91	5.3
7029	0.19	9	0.24	95	65	94	6.2
7030	0.17	12	0.23	78	66	111	5.7

Group 2: 512 mg/kg/day of test substance compared to 250 mg/kg/day of the active ingredient  
 Group 1: 1024 mg/kg/day of test substance compared to 500 mg/kg/day of the active ingredient  
 Group 1: 1536 mg/kg/day of test substance compared to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Lecthemoglobin Preparation: A 28-Day Dietary Study in Rats

INSTITUTION: Andhra Pradesh Veterinary College

Sex: Male Days(s) Relative to Start Date

512 mg/kg/day Group 2	Olivetone Chlor Plus						
	ALB	GLOB	CALC	TPHS	NA	K	CL
	(mg/dL)	(g/dL)	(mg/dL)	(mg/dL)	(mmol/L)	(mmol/L)	(mmol/L)
22	22	22	22	22	22	22	22
7021	3.4	2.8	11.0	9.3	142.5	4.90	100.8
7022	3.1	2.6	10.5	8.2	141.6	5.05	101.2
7023	3.3	3.1	10.5	9.0	141.7	5.27	101.5
7024	3.2	2.9	10.3	8.1	141.3	5.13	101.8
7025	3.1	2.9	10.3	9.0	141.9	5.35	102.6
7026	3.1	2.8	10.3	8.6	142.0	5.34	102.6
7027	3.0	3.0	10.1	8.8	142.4	5.25	102.8
7028	3.4	2.9	10.3	8.5	143.2	5.66	102.2
7029	3.3	2.9	10.5	8.9	141.5	4.73	100.7
7030	3.2	2.5	10.3	8.4	143.0	5.18	103.6

Group 1: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
 Group 2: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
 Group 3: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Sex: Leghemoglobin Preparation - A 28-Day Dietary Study in Rats

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Sex: Male Days Relative to Start Date

1024 mg/kg/day Group 3	Chemical (Chem. Pks)						
	BILM	LIP	LT	AST	ALT	BUN	ALKP
	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)
	22	22	22	22	22	22	22
7001	None	None	None	81	24	74	181
7002	None	None	None	76	22	72	206
7003	Trace	None	None	NPH	24	NPH	198
7004	None	None	None	86	24	130	227
7005	Trace	None	None	NPH	24	NPH	208
7006	None	None	None	69	22	88	226
7007	Trace	None	None	NPH	22	NPH	157
7008	None	None	None	87	24	69	207
7009	Trace	None	None	NPH	31	NPH	220
7050	None	None	None	73	31	70	184

Sex: Male Days Relative to Start Date

1024 mg/kg/day Group 3	Chemical (Chem. Pks)						
	BILI	BUN	CREA	CBIL	TRIG	GLUC	TP
	(mg/dL)	(mg/dL)	(mg/dL)	(mg/dL)	(mg/dL)	(mg/dL)	(g/dL)
	22	22	22	22	22	22	22
7001	0.18	10	0.22	71	72	90	8.2
7002	0.17	9	0.22	85	26	107	8.3
7003	0.17	9	0.25	70	27	101	8.5
7004	0.18	10	0.23	73	26	86	6.2
7005	0.15	11	0.26	61	63	109	4.6
7006	0.20	12	0.25	92	73	121	6.6
7007	0.17	9	0.23	73	26	102	6.1
7008	0.15	12	0.23	76	63	83	6.0
7009	0.19	8	0.26	49	4	99	8.1
7050	0.20	10	0.20	75	47	116	6.1

Group 2: 512 mg/kg/day of test substance corresponds to 256 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 512 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 768 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Sep. Leishmanoglybin Preparation - A 28-Day Dietary Study in Rats

INVESTIGATOR: ANANDA CHANDRA PATIL (INDIA) 10/27/2004

Sex: Male Days to Reference to Start Date

1024 mg/kg/day Group 3	Chemical						
	ALB	GLUB	GMA	BPHS	NA	K	CL
	(g/dL)	(g/dL)	(mg/dL)	(mg/dL)	(mmol/L)	(mmol/L)	(mmol/L)
22	22	22	22	22	22	22	
7041	3.3	2.9	10.3	7.5	141.6	5.30	101.2
7042	3.3	3.0	10.9	8.8	140.7	4.79	100.4
7043	3.4	3.1	10.4	NPPI	142.1	4.96	101.3
7044	3.3	2.9	10.5	8.4	140.3	6.83	101.9
7045	3.2	2.8	10.7	NPPI	140.7	5.47	101.9
7046	3.1	2.9	10.2	8.6	139.9	5.72	101.8
7047	3.3	3.1	10.6	NPPI	140.8	5.52	100.4
7048	3.3	2.7	10.4	10.0	142.0	5.11	101.7
7049	3.3	2.8	10.1	NPPI	141.3	6.28	102.9
7050	3.2	2.9	10.3	9.4	141.4	5.55	102.6

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient



Clinical Pathology Results for  
Soy Leucine/lysine Preparation - A 28-Day Dietary Study in Rats

Department: Animal Health and Husbandry

Sex: Male Days Relative to Start Date

1536 mg/kg/day Group 4	Chemistry (Chem Pks)						
	BUN	CLP	CT	AST	ALT	SEB	ALKP
	(mg/dL)	(mg/dL)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)
	22	22	22	22	22	22	22
7061	None	None	None	81	32	7.9	198
7062	Trace	None	None	NPH	32	NPH	189
7063	None	None	None	83	33	7.9	267
7064	None	None	None	77	33	8.6	235
7065	None	None	None	93	32	5.2	181
7066	None	None	None	65	24	8.4	180
7067	Trace	None	None	NPH	25	NPH	222
7068	None	None	None	73	27	10.2	257
7069	None	None	None	77	23	7.3	125
7070	None	None	None	76	33	8.7	196

Sex: Male Days Relative to Start Date

1536 mg/kg/day Group 4	Chemistry (Chem Pks)						
	BUN	BUN	CREA	CHOL	TRIG	GLUC	TP
	(mg/dL)	(mg/dL)	(mg/dL)	(mg/dL)	(mg/dL)	(mg/dL)	(g/dL)
	22	22	22	22	22	22	22
7061	0.12	11	0.21	52	56	105	6.1
7062	0.19	9	0.25	61	45	92	6.1
7063	0.20	11	0.21	71	88	108	6.1
7064	0.19	7	0.19	70	78	100	6.0
7065	0.20	11	0.21	68	54	81	5.8
7066	0.18	12	0.22	73	92	102	6.1
7067	0.18	12	0.22	85	116	101	6.1
7068	0.20	10	0.23	46	47	92	6.3
7069	0.16	11	0.17	62	33	103	5.4
7070	0.17	11	0.18	83	68	91	6.1

Group 1: 512 mg/kg/day of test substance compared to 250 mg/kg/day of the active ingredient  
 Group 2: 1024 mg/kg/day of test substance compared to 500 mg/kg/day of the active ingredient  
 Group 3: 1536 mg/kg/day of test substance compared to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leptoglobulin Preparation: A 28-Day Dietary Study in Rats

Individual Animal Clinical Pathology Data

Sex: Male Day(s) Relative to Start Date

1536 mg/kg-day Group 1	Chemistry Chem Plus						
	ALB	GLAB	CAU2	BUN	NA	K	CL
	(g/dL)	(g/dL)	(mg/dL)	(mg/dL)	(mmol/L)	(mmol/L)	(mmol/L)
22	22	22	22	22	22	22	
7061	3.2	2.9	10.3	7.8	142.2	4.03	101.7
7062	3.3	2.8	10.2	NPH	142.6	5.41	102.2
7063	3.3	2.8	10.3	8.8	142.1	5.04	103.9
7064	3.3	2.7	10.5	8.9	142.3	5.29	103.6
7065	3.1	2.7	10.8	8.9	140.1	5.21	103.1
7066	3.0	3.1	10.8	8.6	141.9	5.01	103.5
7067	3.1	3.0	10.7	NPH	140.6	5.09	101.0
7068	3.4	2.9	10.7	8.8	141.8	4.81	103.3
7069	3.1	2.4	10.1	8.4	142.2	5.42	104.1
7070	3.2	2.9	10.6	8.4	141.6	4.71	101.3

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Clinical Pathology Results for  
Soy L-tyrosine/tyrosine Preparation - A 28-Day Dietary Study in Rats

Individual Animal Data - Female Data

ID (mg/kg/day) (Group)	Sex: Female Days Relative to Start Date						
	Chemical Panel						
	BUN	GLP	BPT	AST	ALT	SGPT	ALP
	(mg/dL)	(mg/dL)	(mg/dL)	(IU/L)	(IU/L)	(IU/L)	(IU/L)
	22	22	22	22	22	22	22
7011	None	None	None	78	33	7.9	152
7012	None	None	None	66	26	5.8	112
7013	None	None	None	78	25	6.7	134
7014	None	None	None	74	21	6.3	112
7015	None	None	None	66	21	7.6	111
7016	None	None	None	59	25	11.0	151
7017	None	None	None	69	23	8.5	131
7018	None	None	None	68	24	8.6	155
7019	Trace	None	None	NPH	27	NPH	140
7020	None	None	None	66	27	13.0	139

ID (mg/kg/day) (Group)	Sex: Female Days Relative to Start Date						
	Chemical Panel						
	BUN	BUN	CREA	CRCL	BUN	GLUC	TP
	(mg/dL)	(mg/dL)	(mg/dL)	(mg/dL)	(mg/dL)	(mg/dL)	(g/dL)
	22	22	22	22	22	22	22
7011	0.18	12	0.29	82	31	116	6.3
7012	0.18	13	0.26	87	31	116	6.7
7013	0.23	12	0.29	85	47	123	6.8
7014	0.16	15	0.29	76	33	150	6.8
7015	0.17	14	0.32	71	41	126	6.3
7016	0.10	11	0.29	90	39	99	6.3
7017	0.15	12	0.25	98	14	105	6.0
7018	0.16	12	0.26	85	32	121	6.5
7019	0.26	12	0.27	102	32	103	6.2
7020	0.19	9	0.24	69	30	118	6.6

Group 1: 512 mg/kg/day of the substance corresponds to 250 mg/kg/day of the active ingredient  
 Group 2: 1024 mg/kg/day of the substance corresponds to 500 mg/kg/day of the active ingredient  
 Group 3: 1536 mg/kg/day of the substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Sex 1, eg, hemoglobin Preparation: A 28-Day Dietary Study in Rats

15/11/2006 08:00:00 1/10/2006 10:00:00

Sex: Female Dept(s) Relative to Stan Date:

ID mg/kg/day Group 1	Chemical/Chem Phys						
	ALB	GLU/B	CALC	IPHS	NA	K	CL
	g/dL	g/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L
22	22	22	22	22	22	22	
7011	3.6	2.9	10.3	7.3	139.4	4.64	102.0
7012	3.7	3.0	10.7	6.8	140.8	4.15	102.7
7013	3.8	3.0	10.8	7.3	139.4	4.90	103.5
7014	3.7	3.1	10.4	6.6	141.6	4.21	105.2
7015	3.5	2.8	9.9	6.8	139.8	4.14	102.0
7016	3.4	2.9	10.6	7.1	138.5	4.35	101.2
7017	3.3	2.7	10.7	7.9	140.9	5.14	103.8
7018	3.5	3.0	10.8	7.6	140.5	4.63	103.0
7019	3.3	2.9	10.5	NFI	139.6	4.71	102.0
7020	3.3	2.7	10.3	6.6	141.2	4.62	102.6

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
 Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
 Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Sex: Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

Individual Results (continued)

Sex: Female Days Relative to Start Date

SID mg/kg/day Group 2	Oxycortin Chlor Phos						
	HEM	CLP	ICT	AST (U/L)	ALT (U/L)	BLDH (U/L)	ALKP (U/L)
	22	22	22	22	22	22	22
7031	None	None	None	71	54	8.7	97
7032	None	None	None	78	22	8.6	111
7033	None	None	None	78	27	9.7	121
7034	None	None	None	59	26	8.3	115
7035	None	None	None	63	19	9.4	98
7036	None	None	None	58	24	6.1	135
7037	None	None	None	87	32	7.4	102
7038	None	None	None	70	31	8.3	127
7039	None	None	None	NPH	20	NPH	90
7040	None	None	None	58	24	6.8	70

Sex: Female Days Relative to Start Date

SID mg/kg/day Group 2	Oxycortin Chlor Phos						
	BLI (mg/dL)	BUN (mg/dL)	CREA (mg/dL)	CEROL (mg/dL)	TRIG (mg/dL)	GLUC (mg/dL)	TP (g/dL)
	22	22	22	22	22	22	22
7031	0.20	10	0.21	97	29	91	6.8
7032	0.19	9	0.25	117	47	89	6.9
7033	0.20	11	0.26	71	27	111	7.1
7034	0.21	11	0.26	97	44	105	7.4
7035	0.16	11	0.28	78	30	95	6.4
7036	0.20	12	0.26	91	34	97	6.7
7037	0.20	9	0.22	89	31	95	6.1
7038	0.18	11	0.27	85	42	115	6.4
7039	0.21	10	0.25	137	47	118	6.3
7040	0.19	14	0.28	86	32	106	7.0

Group 1: 512 mg/kg/day of the substance corresponds to 250 mg/kg/day of the active ingredient  
Group 2: 1024 mg/kg/day of the substance corresponds to 500 mg/kg/day of the active ingredient  
Group 3: 1536 mg/kg/day of the substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Sex: Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

Individual Animal Data - Hematology Data

Sex: Female mg/kg/day Group 2	Days Relative to Start Date						
	Oleaceo Chem Plus						
	ALB	GLUB	CATC	TPPS	NA	K	CL
(g/dL)	(g/dL)	(mg/dL)	(mg/dL)	(mmol/L)	(mmol/L)	(mmol/L)	(mmol/L)
32	32	32	32	32	32	32	32
7031	3.7	3.1	11.1	7.6	140.3	4.28	101.2
7032	3.5	3.4	11.0	8.3	141.0	5.18	99.7
7033	3.9	3.2	11.0	8.4	139.9	4.76	99.6
7034	4.2	3.2	11.7	8.4	140.1	4.78	99.6
7035	3.5	2.9	10.5	7.5	141.8	4.23	103.3
7036	3.7	3.0	11.2	8.3	140.7	4.48	101.2
7037	3.5	2.9	10.6	7.8	140.8	4.48	101.1
7038	3.5	2.9	10.4	7.1	139.9	5.08	102.9
7039	3.5	2.8	11.2	NPH	141.4	4.82	103.6
7040	3.3	3.5	10.8	6.7	140.2	3.99	101.6

Group 1: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 2: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 3: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Clinical Pathology Results for  
Soy Lecithin/Globin Preparation - A 28-Day Dietary Study in Rats

28-Day Study - Total of 100 Study Data

Sex: Female Days Relative to Start Date

[024] mg/kg/dn Group 3	Olivaceous Churn Plus						
	HEM	LEP	RET	AST	ALT	SEH	ALKP
	(mg/dL)	(mg/dL)	(mg/dL)	(U/L)	(U/L)	(U/L)	(U/L)
	22	22	22	22	22	22	22
7651	None	None	None	73	33	8.7	131
7652	None	None	None	75	36	7.6	152
7653	None	None	None	67	25	8.1	102
7654	None	None	None	58	17	7.6	64
7655	None	None	None	67	29	8.9	113
7656	None	None	None	49	29	6.4	107
7657	None	None	None	60	26	7.9	151
7658	None	None	None	60	28	7.3	106
7659	None	None	None	69	23	9.7	121
7660	None	None	None	66	24	7.8	136

Sex: Female Days Relative to Start Date

[024] mg/kg/dn Group 3	Olivaceous Churn Plus						
	BUN	BUN	CREA	UREA	TRIG	GLUC	IP
	(mg/dL)	(mg/dL)	(mg/dL)	(mg/dL)	(mg/dL)	(mg/dL)	(mg/dL)
	22	22	22	22	22	22	22
7651	0.21	13	0.27	68	32	98	6.5
7652	0.19	15	0.25	71	21	97	6.8
7653	0.17	16	0.26	116	40	98	7.3
7654	0.19	12	0.13	108	13	107	6.8
7655	0.20	11	0.26	82	66	127	6.9
7656	0.25	14	0.27	90	41	113	6.6
7657	0.20	13	0.27	106	28	101	6.4
7658	0.20	10	0.28	117	22	96	7.2
7659	0.17	12	0.28	161	57	98	6.6
7660	0.20	11	0.21	129	42	103	6.6

Group 2: 512 mg/kg/day of the substance corresponds to 250 mg/kg/day of the active ingredients  
Group 3: 1024 mg/kg/day of the substance corresponds to 500 mg/kg/day of the active ingredients  
Group 4: 1536 mg/kg/day of the substance corresponds to 750 mg/kg/day of the active ingredients

Clinical Pathology Results for  
Soy Lecithin Preparation - A 28-Day Dietary Study in Rats

INSTITUTION: ANLAPL 1116 14 14/10/2007 1:04

Sex: Female Day(s) Relative to Start Date:

1024 mg/kg/day Group 3	Chemistry Chem Phys						
	ALB (g/dL)	GLOB (g/dL)	CALC (mg/dL)	TPHS (mg/dL)	NA (mmol/L)	K (mmol/L)	CL (mmol/L)
	22	22	22	22	22	22	22
1031	3.6	2.9	10.5	7.4	139.7	4.52	100.3
1032	3.7	3.1	10.7	7.0	140.3	4.50	102.4
1033	3.8	3.5	11.4	7.8	140.8	4.38	100.9
1034	3.6	3.2	11.3	7.7	140.1	4.78	100.7
1035	3.8	3.1	10.8	7.0	140.9	4.78	101.1
1036	3.6	3.0	11.1	8.1	140.0	4.53	100.4
1037	3.5	2.9	10.9	7.5	139.7	4.51	101.2
1038	3.6	3.2	11.5	7.4	140.3	4.69	100.9
1039	3.5	3.1	11.0	8.2	141.7	4.30	103.3
1040	3.6	3.0	11.2	7.6	139.8	5.02	99.7

Group 1: 517 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 2: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 3: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient



Clinical Pathology Results for  
Sex: Female Hemoglobin Preparation: A 28-Day Dietary Study in Rats

Individual Animal Data (continued)

1536 mg/kg/day (Group 1)	Days Relative to Start Date						
	Chemical Data (µg/dL)						
	HEM	HP	HCT	AST	ALT	SGPT	ALP
	22	22	22	22	22	22	22
5071	None	None	None	70	24	7.3	88
5072	None	None	None	69	31	8.7	148
5073	None	None	None	74	38	12.7	78
5074	None	None	None	64	17	8.9	78
5075	None	None	None	61	28	8.2	115
5076	None	None	None	57	24	11.4	90
5077	None	None	None	62	27	8.3	110
5078	None	None	None	56	26	7.5	104
5079	None	None	None	68	27	15.2	149
5080	None	None	None	87	23	10.2	117

1536 mg/kg/day (Group 1)	Days Relative to Start Date						
	Chemical Data (µg/dL)						
	BUN	BUN	CREA	UREA	TRIG	GLUC	TP
	22	22	22	22	22	22	22
5071	0.20	11	0.25	81	29	100	6.4
5072	0.18	12	0.26	79	29	95	6.6
5073	0.20	12	0.32	128	43	106	7.3
5074	0.19	13	0.41	190	41	157	7.2
5075	0.22	13	0.26	130	36	100	6.5
5076	0.20	11	0.25	61	27	103	6.1
5077	0.19	10	0.25	127	52	106	6.6
5078	0.13	13	0.26	89	31	100	6.3
5079	0.22	13	0.31	89	35	130	6.5
5080	0.20	14	0.32	94	30	123	6.5

Group 2: 512 mg/kg/day of test substance corresponds to 790 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 590 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 790 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

Individual Animal Clinical Pathology Data

Sex: Female Day(s) Relative to Start Date

US26 mg/kg/day Group 4	Oximus Chem Panel						
	ALB	GLDH	CALZ	TPH5	NA	K	CL
	g/dL	g/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L
22	22	22	22	22	22	22	22
7071	3.6	2.9	10.5	6.9	139.3	5.21	102.8
7072	3.5	3.1	10.5	6.9	138.0	5.18	101.8
7073	4.1	3.2	11.1	7.3	136.9	4.66	101.3
7074	3.9	3.3	10.8	6.3	141.2	4.29	102.9
7075	3.9	3.0	11.1	6.9	141.7	4.37	101.3
7076	3.3	2.8	10.6	7.6	130.3	4.99	103.3
7077	3.6	3.0	11.1	8.0	139.8	5.21	99.8
7078	3.3	3.0	10.9	8.6	142.3	4.64	103.0
7079	3.5	3.0	10.3	5.7	139.7	4.54	102.1
7080	3.6	2.9	10.0	6.5	140.2	4.29	102.8

Group 2: 312 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient  
 Group 3: 1021 mg/kg/day of test substance corresponds to 2501 mg/kg/day of the active ingredient  
 Group 4: 1755 mg/kg/day of test substance corresponds to 700 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Lecithin Lecithin Preparation - A 28-Day Dietary Study in Rats

Individual Results: 10/10 of 10/10 Study Data

Sex: Male Days Relative to Start Date

ID	COAGULAN						
	QUAL	COUL	CLAR	UVOL	pH	SD	INLC
	22	22	22	22	22	22	22
mg/kg/dry stomach			ml				mg/dl
7001	Light	Yellow	Clear	2.4	6.0	1.072	NEGATIVE
7002	Light	Yellow	Hazy	8.2	6.0	1.029	NEGATIVE
7003	Light	Yellow	Clear	9.6	6.5	1.024	NEGATIVE
7004	Light	Yellow	Clear	6.0	6.5	1.027	NEGATIVE
7005	Light	Yellow	Clear	16.8	6.5	1.013	NEGATIVE
7006	Light	Yellow	Clear	7.2	6.5	1.026	NEGATIVE
7007	Light	Yellow	Clear	18.2	7.0	1.016	NEGATIVE
7008	Light	Yellow	Clear	14.0	6.5	1.016	NEGATIVE
7009	Medium	Yellow	Hazy	5.6	6.5	1.013	NEGATIVE
7010	Light	Yellow	Clear	9.0	7.0	1.008	NEGATIVE

Group 2: 212 mg/kg/day of test substance corresponds to 290 mg/kg/day of the active ingredient  
 Group 7: 1024 mg/kg/day of test substance corresponds to 900 mg/kg/day of the active ingredient  
 Group 4: 1556 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leghemelectin Preparation - A 28-Day Dietary Study in Rats

INDIVIDUAL RESULTS - CLINICAL PATHOLOGY DATA

Sex: Male Days Relative to Start Date

ID mg/kg/day (Group)	HYPATHEAS				Chemical Assay Pla
	KET	URIL	BLD	PRO	UMTP
	(mp/dL)			(U/L)	(mp/dL)
	22	22	22	22	22
2000	TRACE	NEGATIVE	NEGATIVE	1.6	196
2002	TRACE	NEGATIVE	NEGATIVE	0.2	115
2003	15	NEGATIVE	NEGATIVE	0.2	84
2004	15	NEGATIVE	NEGATIVE	0.2	85
2005	NEGATIVE	NEGATIVE	LARGE	0.2	46
2006	15	NEGATIVE	NEGATIVE	0.2	129
2007	NEGATIVE	NEGATIVE	TRACE	0.2	63
2008	TRACE	NEGATIVE	LARGE	0.2	50
2009	15	NEGATIVE	TRACE	0.2	174
2010	NEGATIVE	NEGATIVE	NEGATIVE	0.2	98

Group 2: 50 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 100 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 150 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Lecithin Preparation - A 28-Day Dietary Study in Rats

CONTRACT NUMBER: 1001-0101-0001

Sex: Male Days Relative to Start Date

502 mg/kg/day (Group 2)	urinalysis						
	QUAL	COLO	CLAR	UVOL	pH	SG	LABU
	22	22	22	22 mL/d	22	22	22 mg/dL
7021	Light	Yellow	Hazy	4.8	6.0	1.042	NEGATIVE
7022	Light	Yellow	Cloudy	9.6	7.0	1.024	NEGATIVE
7023	Light	Yellow	Hazy	6.0	6.5	1.031	NEGATIVE
7024	Light	Yellow	Clear	4.0	6.0	1.052	NEGATIVE
7025	Light	Yellow	Clear	15.4	7.0	1.015	NEGATIVE
7026	Light	Yellow	Clear	29.0	6.5	1.011	NEGATIVE
7027	Light	Yellow	Clear	15.8	6.5	1.017	NEGATIVE
7028	Light	Yellow	Clear	0.1	QNS	QNS	QNS
7029	Light	Yellow	Hazy	26.0	7.0	1.013	NEGATIVE
7030	Light	Yellow	Clear	4.6	6.0	1.040	NEGATIVE

Group 2: 502 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
 Group 3: 1021 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
 Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leghemoglobin Preparation - A 28-Day Dietary Study in Rats

Individual Results - Clinical Pathology Data

Sex: Male mg/kg/day (Group 2)	Days Relative to Start Date				
	KE7 (mg/dL)	URIL (mg/dL)	BLD (mg/dL)	URO (mg/dL)	Chemical Chem Ph (mg/dL)
7021	TRACE	NEGATIVE	TRACE	0.2	122
7022	TRACE	NEGATIVE	LARGE	0.2	116
7023	15	NEGATIVE	NEGATIVE	0.2	205
7024	NEGATIVE	NEGATIVE	NEGATIVE	0.2	250
7025	NEGATIVE	NEGATIVE	NEGATIVE	0.2	133
7026	NEGATIVE	NEGATIVE	TRACE	0.2	38
7027	TRACE	NEGATIVE	NEGATIVE	0.2	38
7028	QNS	QNS	QNS	QNS	1280
7029	TRACE	NEGATIVE	NEGATIVE	0.2	21
7030	TRACE	NEGATIVE	NEGATIVE	0.2	185

Group 2: 15 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
 Group 3: 100 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
 Group 4: 150 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Sex: Male Days to Reference to Start Date

Individual Results Table 03/11/2021 08:14

1021 mg/kg/day Group 2	uvol/ALLAS						
	QUAL	COLOR	CLAR	UVOL	pH	SG	UMLC
	22	22	22	22	22	22	22
7041	Light	Yellow	Clear	24.1	7.0	1.011	NEGATIVE
7042	Light	Yellow	Clear	9.8	6.5	1.024	NEGATIVE
7043	Light	Yellow	Clear	4.2	6.0	1.042	NEGATIVE
7044	Light	Yellow	Clear	15.0	6.5	1.017	NEGATIVE
7045	Light	Yellow	Heavy	22.0	7.0	1.012	NEGATIVE
7046	Light <sup>1)</sup>	Brown <sup>1)</sup>	Cloudy <sup>1)</sup>	3.6 <sup>1)</sup>	6.5 <sup>1)</sup>	1.054 <sup>1)</sup>	NEGATIVE <sup>1)</sup>
7047	Light	Yellow	Clear	13.0	6.0	1.022	NEGATIVE
7048	Light	Yellow	Heavy	11.0	6.5	1.026	NEGATIVE
7049	Light	Yellow	Clear	7.0	6.5	1.023	NEGATIVE
7050	Light	Yellow	Clear	9.0	7.0	1.024	NEGATIVE

1 USC: Fecal contamination observed

Group 2: 212 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 5: 1071 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 7: 1330 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leishemoglobin Preparation: A 28-Day Dietary Study in Rats

Continuation of Table 1 from Pathology Report

Sex: Male Days Relative to Start Date

1021 mg/kg/day (Group 3)	Hematology				Chemical Clotting Parameters	
	RET (imp/dL)	CHH (%)	BLD (%)	URO (%)	PT (sec)	APTT (sec)
7040	TRACE	NEGATIVE	TRACE	0.2	34	
7042	TRACE	NEGATIVE	NEGATIVE	0.2	61	
7043	TRACE	NEGATIVE	SMALL	0.2	230	
7044	NEGATIVE	NEGATIVE	SMALL	0.2	103	
7045	TRACE	NEGATIVE	MODERATE	0.2	65	
7046	15 "	SMALL "	LARGE "	1.0 "	290	
7047	TRACE	NEGATIVE	NEGATIVE	0.2	159	
7048	15	NEGATIVE	MODERATE	0.2	166	
7049	TRACE	NEGATIVE	TRACE	0.2	98	
7050	TRACE	NEGATIVE	MODERATE	0.2	93	

1 (SC: Fecal contamination observed)

Group 2: 312 mg/kg/day of test substance corresponds to 290 mg/kg/day of the active ingredient  
Group 3: 307 mg/kg/day of test substance corresponds to 280 mg/kg/day of the active ingredient  
Group 4: 150 mg/kg/day of test substance corresponds to 130 mg/kg/day of the active ingredient



Clinical Pathology Results for  
Soy Lectin/lecithin Preparations - A 28-Day Dietary Study in Rats

CLINICAL PATHOLOGY DATA - FEMALE RATS

Sex: Male Days Relative to Start Date

USP mg/kg/day Group #	WOBLETTAS						
	SQUAL	EXOL	CLAR	UVOL	pH	SO	COLI <sup>2</sup>
	uL						amp/LL
22	22	22	22	22	22	22	22
7061	Light	Yellow	Hazy	15.8	6.5	1029	NEGATIVE
7062	Light	Yellow	Clear	11.8	6.5	1019	NEGATIVE
7063	Light	Yellow	Clear	16.2	6.5	1024	NEGATIVE
7064	Light	Yellow	Clear	21.9	7.0	1011	NEGATIVE
7065	Light	Yellow	Clear	16.0	6.0	1018	NEGATIVE
7066	Light	Yellow	Hazy	15.4	7.0	1017	NEGATIVE
7067	Medium "	Yellow "	Cloudy "	9.6 "	7.0 "	1022 "	NEGATIVE "
7068	Light	Yellow	Clear	12.8	6.5	1016	NEGATIVE
7069	Light	Yellow	Clear	1.0	6.0	1026	NEGATIVE
7070	Light	Yellow	Hazy	19.6	7.0	1015	NEGATIVE

YUSC: Fecal contamination observed

Group 2: 212 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 105 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 153 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leghemoglobin Preparations: A 28-Day Dietary Study in Rats

Continued from Table 1 of PSL Study 43166

Sex: Male Days (Relative to Start Date)

Dose (mg/kg/day) (Group #)	Hemolysis				Chemical UMPP (mg/dL)
	KET (mg/dL)	UBB	BLD	URO (mg/dL)	
22	22	22	22	22	22
701	TRACE	NEGATIVE	SMALL	0.2	77
702	NEGATIVE	NEGATIVE	NEGATIVE	0.2	63
703	15	NEGATIVE	NEGATIVE	0.2	120
704	NEGATIVE	NEGATIVE	MODERATE	0.2	48
705	NEGATIVE	NEGATIVE	SMALL	0.2	53
706	NEGATIVE	NEGATIVE	LARGE	0.2	97
707	15	NEGATIVE	LARGE	0.2	108
708	TRACE	NEGATIVE	SMALL	0.2	92
709	NEGATIVE	NEGATIVE	NEGATIVE	0.2	380
710	TRACE	NEGATIVE	LARGE	0.2	55

1 USC Fecal contamination observed.

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 7: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 1: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Clinical Pathology Results for  
Soy Lecithin Lecithin Preparation - A 28-Day Dietary Study in Rats

2019/06/04 09:00:00 - 11:00:00 AM EDT

Sex: Female Days Relative to Start Date:

ID mg/kg/day (Group 1)	WHA/BLAS						
	QUANT.	COLOR	CLAR.	LEVEL	pH	SG	LEUC
	mg/dL	mg/dL	mg/dL	mg/dL	mg/dL	mg/dL	mg/dL
7011	Light	Yellow	Clear	0.5	6.0	1.001 <sup>1)</sup>	NEGATIVE
7012	Light	Yellow	Clear	1.2	6.0	1.039	NEGATIVE
7013	Light	Yellow	Hazy	2.6	6.5	1.025	NEGATIVE
7014	Light	Yellow	Hazy	3.6	7.0	1.038	NEGATIVE
7015	Light	Yellow	Clear	3.8	6.0	1.047	NEGATIVE
7016	Light	Yellow	Clear	18.2	6.5	1.012	NEGATIVE
7017	Light	Yellow	Clear	15.4	6.5	1.016	NEGATIVE
7018	Light	Yellow	Clear	0.0	6.5	1.058	NEGATIVE
7019	Light	Yellow	Clear	15.0	6.0	1.013	NEGATIVE
7020	Medium	Yellow	Cloudy	8.6	7.0	1.025	NEGATIVE

1 BGC. Specific gravity result is <math>= 1.100</math>

Group 2: 502 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 509 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 760 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leghämoglobin Preparation - A 28-Day Dietary Study in Rats

199913-0001 000004 110609 1410 0029 0004

Sex: Female Days Relative to Start Date

n mg/kg/day (Group 1)	Urinalysis					Chemical Screen UMTF
	KET	UBI	BLD	URO		
	(mg/dL)			(mg/dL)	(mg/dL)	
	22	22	22	22	22	
001	NEGATIVE	SMALL	NEGATIVE	0.2		127
002	NEGATIVE	NEGATIVE	NEGATIVE	0.2		34
003	NEGATIVE	NEGATIVE	TRACE	0.2		35
004	NEGATIVE	NEGATIVE	SMALL	0.2		37
005	NEGATIVE	NEGATIVE	NEGATIVE	0.2		47
006	NEGATIVE	NEGATIVE	NEGATIVE	0.2		44
007	NEGATIVE	NEGATIVE	NEGATIVE	0.2		9
008	NEGATIVE	NEGATIVE	LARGE	0.2		69
009	NEGATIVE	NEGATIVE	NEGATIVE	0.2		22
009	NEGATIVE	NEGATIVE	MODERATE	0.2		38

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1624 mg/kg/day of test substance corresponds to 800 mg/kg/day of the active ingredient  
Group 4: 4550 mg/kg/day of test substance corresponds to 2250 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Lecithemoglobin Preparation: A 28-Day Dietary Study in Rats

CONVENTIONAL BUNDOX: 1110-01-1110-1024 (04)

Sex: Female Days Relative to Start Date

SID mg/kg/dry through 2	uvcdALLAS						
	QUAL	COLOR	CLAR	UVIS	pH	SG	UMLC
	22	22	22	22	22	22	22
7031	Light	Yellow	Clear	5.8	6.0	1.031	NEGATIVE
7032	Light	Yellow	Hazy	12.4	7.0	1.013	NEGATIVE
7033	Light	Yellow	Clear	1.0	6.0	1.026	NEGATIVE
7034	Light	Yellow	Hazy	7.6	6.5	1.029	NEGATIVE
7035	Light	Yellow	Clear	11.2	6.0	1.011	NEGATIVE
7036	Light	Yellow	Clear	16.8	6.5	1.011	NEGATIVE
7037	Light	Yellow	Clear	2.8	6.0	1.049	NEGATIVE
7038	Medium	Yellow	Hazy	3.6	6.6	1.051	NEGATIVE
7039	Light	Yellow	Clear	4.0	6.0	1.036	NEGATIVE
7040	Light	Yellow	Clear	3.0	5.5	1.052	NEGATIVE

Group 2: 212 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
 Group 3: 1054 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
 Group 4: 1580 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

Individual Animal Clinical Pathology Data

Sex: Female Days Relative to Start Date

SID mg/kg/day (Group 2)	myo-AEAS				Urea Nitrogen (BUN)	Urea Phosphorus (BUNP)
	KE7 (mg/dL)	EBL	BLD	PRO	(mg/dL)	(mg/dL)
001	TRACE	NEGATIVE	NEGATIVE	0.2		35
002	NEGATIVE	NEGATIVE	MODERATE	0.2		17
003	NEGATIVE	NEGATIVE	NEGATIVE	0.2		90
004	NEGATIVE	NEGATIVE	MODERATE	0.2		29
005	NEGATIVE	NEGATIVE	NEGATIVE	0.2		16
006	NEGATIVE	NEGATIVE	NEGATIVE	0.2		14
007	TRACE	SMALL	SMALL	0.2		35
008	TRACE	SMALL	MODERATE	0.2		61
009	TRACE	NEGATIVE	NEGATIVE	0.2		41
040	NEGATIVE	NEGATIVE	MODERATE	0.2		65

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
 Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
 Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Lecithemeglebin Preparation - A 28-Day Dietary Study in Rats

Individual Results from 10/13/19 to 12/13/19

Sex: Female Days Relative to Start Date

1021 mg/kg/day Group 2	ovaB/H/LAS						
	QUAL	COLOR	CLAR	UVCL	pH	SG	COAG
	22	22	22	22	22	22	22
				ml/c			mg/dL
7051	Medium	Yellow	Hazy	3.0	6.9	1.046	NEGATIVE
7052	Light	Yellow	Clear	3.6	6.0	1.043	NEGATIVE
7053	Light	Yellow	Cloudy	8.0	7.0	1.021	NEGATIVE
7054	Light	Yellow	Clear	0.08	6.0	1.017	NEGATIVE
7055	Light	Yellow	Clear	3.0	6.5	1.040	NEGATIVE
7056	Light	Yellow	Clear	10.2	6.5	1.029	NEGATIVE
7057	Medium *	Brown *	Turbid *	1.0 *	7.5 *	1.028 *	NEGATIVE *
7058	Medium	Yellow	Cloudy	7.0	7.0	1.022	NEGATIVE
7059	Light *	Brown *	Cloudy *	9.6 *	7.5 *	1.017 *	NEGATIVE *
7060	Light	Yellow	Clear	6.2	6.0	1.027	NEGATIVE

[15% Fecal contamination observed]

Group 2: 212 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1071 mg/kg/day of test substance corresponds to 990 mg/kg/day of the active ingredient  
Group 4: 1530 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Lecithin Lecithin Preparations: A 28-Day Dietary Study in Rats

Individual Results: Urinary Pathology Data

Sex: Female (Day(s) Relative to Start Date)

1021 mg/kg/day Group 3	myo-ALP AS					Chemical Chem. Phi
	KET	UBB	BLD	URO	UMTP	
	(mg/dL)			(U/L)	(mg/dL)	
	22	22	22	22	22	
7051	TRACE	SMALL	LARGE	0.2		43
7052	NEGATIVE	NEGATIVE	NEGATIVE	0.2		41
7053	TRACE	NEGATIVE	LARGE	0.2		41
7054	NEGATIVE	NEGATIVE	NEGATIVE	0.2		45
7055	NEGATIVE	NEGATIVE	NEGATIVE	0.2		40
7056	NEGATIVE	NEGATIVE	NEGATIVE	0.2		20
7057	TRACE <sup>1</sup>	SMALL <sup>1</sup>	LARGE <sup>1</sup>	0.2 <sup>1</sup>		56
7058	NEGATIVE	NEGATIVE	LARGE	0.2		32
7059	NEGATIVE <sup>1</sup>	NEGATIVE <sup>1</sup>	LARGE <sup>1</sup>	0.2 <sup>1</sup>		35
7060	NEGATIVE	NEGATIVE	LARGE	0.2		20

<sup>1</sup> US: Fecal contamination observed.

Group 2: 212 mg/kg/day of test substance corresponds to 290 mg/kg/day of the active ingredient  
Group 3: 1021 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 740 mg/kg/day of the active ingredient



Clinical Pathology Results for  
Soy Lecithemoglobin Preparation - A 28-Day Dietary Study in Rats

Investigator: [redacted] Date: 03/14/2012 Page: 1

Sex: Female Day(s) Relative to Start Date:

1536 mg/kg/day Group 4	ANALYSIS						
	QUAL	COLOR	CLAR	UVVOL (mL)	pH	SG	IMLZ
	22	22	22	22	22	22	22
7071	Light "	Brown "	Cloudy "	7.8 "	7.6 "	1.024 "	NEGATIVE "
7072	Light	Yellow	Clear	7.8	6.0	1.022	NEGATIVE
7073	Light	Yellow	Clear	5.0	6.0	1.026	NEGATIVE
7074	Light	Yellow	Clear	2.6	6.0	1.016	NEGATIVE
7075	Light	Yellow	Clear	12.8	6.0	1.014	NEGATIVE
7076	Light	Yellow	Clear	3.0	6.0	1.056	NEGATIVE
7077	Medium	Yellow	Dirty	7.0	6.5	1.027	NEGATIVE
7078	Light	Yellow	Clear	14.0	6.5	1.014	NEGATIVE
7079	Dark "	Brown "	Fatmil "	4.0 "	8.0 "	1.031 "	NEGATIVE "
7080	Light	Yellow	Clear	2.2	6.5	1.039	NEGATIVE

[ 15% Fecal contamination observed ]

Group 2: 212 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leghemoglobin Preparation - A 28-Day Dietary Study in Rats

Continuation of Tables 1 and 2 of Pathology Data

Sex: Female Days: Relative to Start Date

USN mg/kg/day Group 4	Urinalysis				Chemical UMIT
	KET (mg/dL)	GBL (mg/dL)	BLD (mg/dL)	URE (mg/dL)	
001	NEGATIVE <sup>1</sup>	NEGATIVE <sup>1</sup>	LARGE <sup>1</sup>	0.2 <sup>1</sup>	47
002	NEGATIVE	NEGATIVE	SMALL	0.2	23
003	NEGATIVE	NEGATIVE	TRACE	0.2	42
004	NEGATIVE	NEGATIVE	MODERATE	0.2	49
005	NEGATIVE	NEGATIVE	SMALL	0.2	15
006	NEGATIVE	NEGATIVE	NEGATIVE	0.2	59
007	NEGATIVE	NEGATIVE	LARGE	0.2	38
008	NEGATIVE	NEGATIVE	LARGE	0.2	15
009	TRACE <sup>1</sup>	MODERATE <sup>1</sup>	LARGE <sup>1</sup>	1.0 <sup>1</sup>	118
080	NEGATIVE	NEGATIVE	MODERATE	0.2	38

<sup>1</sup> ISC: Fecal examination observed.

Group 1: 512 mg/kg/day of test substance corresponds to 256 mg/kg/day of the active ingredient  
Group 2: 1024 mg/kg/day of test substance corresponds to 512 mg/kg/day of the active ingredient  
Group 3: 1536 mg/kg/day of test substance corresponds to 768 mg/kg/day of the active ingredient

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Clinical Pathology Results for  
Soy Lecithin Emulsion Preparation: A 28-Day Dietary Study in Rats

Urinary Data: Urinalysis (U) by Parameters: UTA

Imp Ag day Group 1	Urinalysis (U) by Parameters: UTA							
	EPIT (hpf)	UVIC (hpf)	URBC (hpf)	SCRV (hpf)	MICR (hpf)	SPER (hpf)	REPI (hpf)	KIDG (hpf)
	22	22	22	22	22	22	22	22
7001	Few	-	-	Few	Few	Mod	-	-
7002	Few	Few	-	Few	Mod	Mod	-	Few
7003	Few	-	-	Few	Few	Mod	-	-
7004	Few	-	-	Few	Few	Few	-	-
7005	Few	-	-	Few	Mod	Few	-	-
7006	Few	-	-	Mod	Mod	Mod	-	-
7007	-	-	-	Few	Few	Few	-	-
7008	-	-	-	-	Few	Few	-	-
7009	Few	Few	-	Mod	Mod	Mod	-	-
7010	Few	-	-	Few	Few	Few	-	-

[USC: urine below recommended volume]  
Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 2558 mg/kg/day of test substance corresponds to 1250 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Lecthemoglobin Preparation: A 28-Day Dietary Study in Rats

Direct flow method of urine analysis

512 mg/kg/day Group 2	Urine Microscopy							
	EPIT	UWBC	URBC	NR/Y	MICR	SPER	REPI	MUC
	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)
	22	22	22	22	22	22	22	22
7021	Few	-	-	Few	Few	Few	-	-
7022	Few	Few	-	Mod	Mod	Mod	-	-
7023	Few	Few	-	Few	Few	Mod	-	-
7024	-	-	-	Few	Few	Few	-	-
7025	Few	-	-	Few	Few	Few	-	-
7026	-	-	-	Few	Few	Few	-	-
7027	Few	Few	-	Few	Mod	Few	-	-
7028	QNS	-	-	-	-	-	-	-
7029	Few	-	-	Few	Few	Few	-	-
7030	Few	-	-	Few	Few	Few	-	-

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Clinical Pathology Results for  
Soy Lectin Hemoglobin Preparations: A 28-Day Dietary Study in Rats

INDUSTRIAL HIGHEST CLINICAL PATHOLOGY DATA

Sex: Male Day(s) Relative to Start Date

1024 mg/kg/day Group 3	Urine Abnormalities							
	HPPT	UVBC	URBC	NOBY	MICR	SPER	REPI	MLCC
	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)
	22	22	22	22	22	22	22	22
7041	Few	-	-	Few	Few	Few	-	-
7042	Few	-	-	-	Few	Few	-	-
7043	Few	Few	-	Few	Few	Few	-	-
7044	Few	Few	-	Few	Mod	Mod	-	-
7045	Few	Few	-	Mod	Mod	Mod	-	-
7046	Few	Few	-	Man	Mod	Mod	-	-
7047	-	-	-	-	Few	Few	-	-
7048	Few	Few	-	Mod	Mod	Mod	-	-
7049	Few	-	-	Few	Few	Few	-	-
7050	Few	-	-	Few	Few	Few	-	-

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 2528 mg/kg/day of test substance corresponds to 1250 mg/kg/day of the active ingredient.

Clinical Pathology (Results for  
Soy Leptoglycin Preparation: A 28-Day Dietary Study in Rats

INDIVIDUAL ANIMAL CLINICAL PATHOLOGY DATA

Sex: Male	153n mg/kg/day Group 4	Day(s) Relative to Start Date							
		Urine Microscopic							
		EPIT	USWBC	URBC	NCRY	MICR	SPER	REPI	MUC
		(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)
		22	22	22	22	22	22	22	22
	7061	-	-	-	-	Few	Few	-	-
	7062	Few	-	-	Few	Few	Few	-	-
	7063	Few	-	-	Few	Few	Few	-	-
	7064	Few	-	-	Few	Mod	Few	-	-
	7065	Few	Few	-	Few	Few	Mod	Few	-
	7066	Few	-	-	Few	Few	Few	-	-
	7067	Few	-	-	Mod	Mod	Mod	-	-
	7068	-	-	-	-	Few	Few	-	-
	7069	Few	Few	Few	Few	Mod	Mod	Mod	Mod
	7070	Few	Few	-	Few	Few	Few	-	-

1:500 (urine below recommended volume)

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Lectin Preparation: A 28-Day Toxicity Study in Rats

Instructions: Summarize Clinical Pathology Data

Sex: Female      Dose(s) Relative to Start Date

In- mg/kg/day Group 1	Urine Microscopic							
	EPIT	CAVPC	URBB	NOBY	MC'R	SPER	REPI	MLX
	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)
	22	22	22	22	22	22	22	22
T011	Few	Few	-	Few	Mod	-	-	-
T012	Few	-	-	Few	Few	-	Few	-
T013	Few	Few	-	Mod	Mod	-	-	-
T014	Few	Few	-	Mod	Mod	-	-	-
T015	Few	Few	-	-	Few	-	-	-
T016	Few	-	-	Few	Few	-	-	-
T017	Few	-	-	-	Few	-	-	-
T018	Few	0	0	Few	Few	0	0	0
T019	Few	-	-	Few	Few	-	-	-
T020	Few	Few	-	Few	Mod	-	-	-

††††† Urine below recommended volume!

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy-Leghemagglutinin Preparation: A 28-Day Dietary Study in Rats

Individual Animal Clinical Pathology Data

Sex: Female Davis) Relative to Start Date

NI2 mg/kg/day Group 2	Urine Microscope							
	EPT	WBC	GRB	NR	MC	SPER	REPI	BLC
	(hp)	(hp)	(hp)	(hp)	(hp)	(hp)	(hp)	(hp)
	22	22	22	22	22	22	22	22
7031	Few	Few	-	Few	Few	-	-	-
7032	Few	-	-	Mod	Mod	-	-	-
7033	Few	Few	-	Few	Few	-	-	-
7034	-	-	-	Few	Mod	-	-	-
7035	Few	Few	-	Few	Mod	-	-	-
7036	-	-	-	Few	Few	-	-	-
7037	Few	Few	-	Few	Mod	-	-	-
7038	Few	-	-	Mod	Mod	-	-	-
7039	-	-	-	Few	Few	-	-	-
7040	Few	-	-	Few	Few	-	-	-

[USC urine below recommended volume]

Group 2: 514 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1028 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1542 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.



Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

INDIVIDUAL ANIMAL CLINICAL PATHOLOGY DATA

Sex: Female Days(s) Relative to Start Date:

1024 mg/kg-day Group 3	Urine Microscopic							
	EPIT	CAVIT	CRBL	NOBY	MCR	SPER	REPI	MBX
	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)
	22	22	22	22	22	22	22	22
7051	Few	Few	-	Few	Mod	-	-	-
7052	Few	-	-	Few	Mod	-	-	-
7053	Few	Few	-	Mod	Mod	-	-	-
7054	Few	Few	-	Mod	Mod	-	-	-
7055	Few	Few	-	Few	Few	-	-	-
7056	Few	-	-	Few	Few	-	-	-
7057	Few	Few	Few	Man	Man	-	-	-
7058	Few	Few	Few	Mod	Man	-	-	-
7059	Few	Few	Few	Man	Man	-	-	-
7060	Few	-	-	Mod	Mod	-	-	-

Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient

Clinical Pathology Results for  
Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

Individual Animal Clinical Pathology Data

Sex: Female Day(s) Relative to Start Date

1536 mg/kg/day Group 4	Urine Microscopic							
	EPIT	WBC	RBC	NCRY	MICR	SPEP	REPI	MUC
	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)	(hpf)
	22	22	22	22	22	22	22	22
7071	Few	Few	-	Min	Min	-	-	Few
7072	Few	-	-	Few	Few	-	-	-
7073	Few	-	-	Few	Few	-	-	-
7074	Few	11	11	Few	Mod	11	11	11
7075	Few	Few	-	Few	Few	-	-	-
7076	Few	-	-	Few	Few	-	-	-
7077	Few	-	-	Few	Mod	-	-	-
7078	Few	-	-	Few	Few	-	-	-
7079	Few	Few	Few	Mod	Mod	-	-	-
7080	Few	-	-	Few	Few	-	-	-

UISC urine below recommended volume!

Group 2: 112 mg/kg/day of test substance corresponds to 290 mg/kg/day of the active ingredient

Group 3: 1024 mg/kg/day of test substance corresponds to 290 mg/kg/day of the active ingredient

Group 4: 1250 mg/kg/day of test substance corresponds to 290 mg/kg/day of the active ingredient

## **APPENDIX O: ANIMAL NUMBERS, DOSE GROUPS, AND FATES<sup>1</sup>**

### **PRODUCT IDENTIFICATION**

Soy Leghemoglobin Preparation

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<sup>1</sup> Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Individual Animal Fates

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Group	Dose Level	Sex	Animal	Cage	Removal Day	Removal Week	Removal Date	Removal Time	Time Slot	Removal Symptom	Pathology Reason
1	0 mg/kg/day	Male	7001	1	29	4	27/10/16	6:50	.	Term	Term
			7002	1	29	4	27/10/16	6:51	.	Term	Term
			7003	2	29	4	27/10/16	6:51	.	Term	Term
			7004	2	29	4	27/10/16	6:51	.	Term	Term
			7005	3	29	4	27/10/16	6:52	.	Term	Term
			7006	3	29	4	27/10/16	6:52	.	Term	Term
			7007	4	29	4	27/10/16	6:52	.	Term	Term
			7008	4	29	4	27/10/16	6:53	.	Term	Term
			7009	5	29	4	27/10/16	6:53	.	Term	Term
			7010	5	29	4	27/10/16	6:53	.	Term	Term
1	0 mg/kg/day	Female	7011	6	30	4	28/10/16	6:50	.	Term	Term
			7012	6	30	4	28/10/16	6:50	.	Term	Term
			7013	7	30	4	28/10/16	6:50	.	Term	Term
			7014	7	30	4	28/10/16	6:51	.	Term	Term
			7015	8	30	4	28/10/16	6:51	.	Term	Term
			7016	8	30	4	28/10/16	6:51	.	Term	Term
			7017	9	30	4	28/10/16	6:52	.	Term	Term
			7018	9	30	4	28/10/16	6:52	.	Term	Term
			7019	10	30	4	28/10/16	6:53	.	Term	Term
			7020	10	30	4	28/10/16	6:53	.	Term	Term
2	512 mg/kg/day	Male	7021	11	29	4	27/10/16	6:56	.	Term	Term
			7022	11	29	4	27/10/16	6:57	.	Term	Term
			7023	12	29	4	27/10/16	6:57	.	Term	Term
			7024	12	29	4	27/10/16	6:57	.	Term	Term
			7025	13	29	4	27/10/16	6:58	.	Term	Term
			7026	13	29	4	27/10/16	6:58	.	Term	Term
			7027	14	29	4	27/10/16	6:59	.	Term	Term
			7028	14	29	4	27/10/16	6:59	.	Term	Term
			7029	15	29	4	27/10/16	6:59	.	Term	Term

Individual Animal Fates

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Group	Dose Level	Sex	Animal	Cage	Removal Day	Removal Week	Removal Date	Removal Time	Time Slot	Removal Symptom	Pathology Reason
2	512 mg/kg/day	Male	7030	15	29	4	27/10/16	7:00	.	Term	Term
2	512 mg/kg/day	Female	7031	16	30	4	28/10/16	6:54	.	Term	Term
			7032	16	30	4	28/10/16	6:54	.	Term	Term
			7033	17	30	4	28/10/16	6:55	.	Term	Term
			7034	17	30	4	28/10/16	6:55	.	Term	Term
			7035	18	30	4	28/10/16	6:55	.	Term	Term
			7036	18	30	4	28/10/16	6:56	.	Term	Term
			7037	19	30	4	28/10/16	6:56	.	Term	Term
			7038	19	30	4	28/10/16	6:56	.	Term	Term
			7039	20	30	4	28/10/16	6:57	.	Term	Term
			7040	20	30	4	28/10/16	6:57	.	Term	Term
3	1024 mg/kg/day	Male	7041	21	29	4	27/10/16	7:00	.	Term	Term
			7042	21	29	4	27/10/16	7:00	.	Term	Term
			7043	22	29	4	27/10/16	7:01	.	Term	Term
			7044	22	29	4	27/10/16	7:01	.	Term	Term
			7045	23	29	4	27/10/16	7:02	.	Term	Term
			7046	23	29	4	27/10/16	7:02	.	Term	Term
			7047	24	29	4	27/10/16	7:03	.	Term	Term
			7048	24	29	4	27/10/16	7:03	.	Term	Term
			7049	25	29	4	27/10/16	7:04	.	Term	Term
			7050	25	29	4	27/10/16	7:04	.	Term	Term
3	1024 mg/kg/day	Female	7051	26	30	4	28/10/16	6:58	.	Term	Term
			7052	26	30	4	28/10/16	6:58	.	Term	Term
			7053	27	30	4	28/10/16	6:58	.	Term	Term
			7054	27	30	4	28/10/16	6:59	.	Term	Term
			7055	28	30	4	28/10/16	6:59	.	Term	Term
			7056	28	30	4	28/10/16	6:59	.	Term	Term
			7057	29	30	4	28/10/16	6:59	.	Term	Term

Individual Animal Fates

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Group	Dose Level	Sex	Animal	Cage	Removal Day	Removal Week	Removal Date	Removal Time	Time Slot	Removal Symptom	Pathology Reason
3	1024 mg/kg/day	Female	7058	29	30	4	28/10/16	7:00	.	Term	Term
			7059	30	30	4	28/10/16	7:00	.	Term	Term
			7060	30	30	4	28/10/16	7:01	.	Term	Term
4	1536 mg/kg/day	Male	7061	31	29	4	27/10/16	7:05	.	Term	Term
			7062	31	29	4	27/10/16	7:05	.	Term	Term
			7063	32	29	4	27/10/16	7:05	.	Term	Term
			7064	32	29	4	27/10/16	7:06	.	Term	Term
			7065	33	29	4	27/10/16	7:06	.	Term	Term
			7066	33	29	4	27/10/16	7:06	.	Term	Term
			7067	34	29	4	27/10/16	7:07	.	Term	Term
			7068	34	29	4	27/10/16	7:07	.	Term	Term
			7069	35	29	4	27/10/16	7:07	.	Term	Term
7070	35	29	4	27/10/16	7:08	.	Term	Term			
4	1536 mg/kg/day	Female	7071	36	30	4	28/10/16	7:01	.	Term	Term
			7072	36	30	4	28/10/16	7:01	.	Term	Term
			7073	37	30	4	28/10/16	7:02	.	Term	Term
			7074	37	30	4	28/10/16	7:02	.	Term	Term
			7075	38	30	4	28/10/16	7:02	.	Term	Term
			7076	38	30	4	28/10/16	7:03	.	Term	Term
			7077	39	30	4	28/10/16	7:03	.	Term	Term
			7078	39	30	4	28/10/16	7:03	.	Term	Term
			7079	40	30	4	28/10/16	7:04	.	Term	Term
			7080	40	30	4	28/10/16	7:04	.	Term	Term

## APPENDIX P: INDIVIDUAL ANIMAL NECROPSY OBSERVATIONS<sup>1</sup>

### PRODUCT IDENTIFICATION

Soy Leghemoglobin Preparation

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<sup>1</sup> Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Individual Animal Necropsy Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

---

Animal: 7001	Group: 1	Sex: Male
	Dose: 0	

---

Necropsy Date: 10/27/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7002	Group: 1	Sex: Male
	Dose: 0	

---

Necropsy Date: 10/27/2016

**Gross Pathology Observations [Correlation]:**

testes-combined : size: 1 x 1.5 cm

testes-combined : right: small; soft

epididymides-combined : size: 3 x 0.5 cm

epididymides-combined : right: small

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7003	Group: 1	Sex: Male
	Dose: 0	

---

Necropsy Date: 10/27/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7004	Group: 1	Sex: Male
	Dose: 0	

---

Necropsy Date: 10/27/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7005	Group: 1	Sex: Male
	Dose: 0	

---

Necropsy Date: 10/27/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7006	Group: 1	Sex: Male
	Dose: 0	

---

Necropsy Date: 10/27/2016



Individual Animal Necropsy Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7007	Group:	1	Sex:	Male
		Dose:	0		

Necropsy Date: 10/27/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7008	Group:	1	Sex:	Male
		Dose:	0		

Necropsy Date: 10/27/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7009	Group:	1	Sex:	Male
		Dose:	0		

Necropsy Date: 10/27/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7010	Group:	1	Sex:	Male
		Dose:	0		

Necropsy Date: 10/27/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7011	Group:	1	Sex:	Female
		Dose:	0		

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7012	Group:	1	Sex:	Female
		Dose:	0		

Necropsy Date: 10/28/2016

---

Individual Animal Necropsy Observations

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A 28-Day Dietary Study in Rats

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7013	Group: 1	Sex: Female
	Dose: 0	

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

uterus : fluid filled

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7014	Group: 1	Sex: Female
	Dose: 0	

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7015	Group: 1	Sex: Female
	Dose: 0	

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7016	Group: 1	Sex: Female
	Dose: 0	

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7017	Group: 1	Sex: Female
	Dose: 0	

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

uterus : fluid filled

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7018	Group: 1	Sex: Female
	Dose: 0	

Individual Animal Necropsy Observations

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Necropsy Date: 10/28/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
uterus: fluid filled		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
Animal: 7019	Group: 1	Sex: Female
	Dose: 0	
Necropsy Date: 10/28/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
No observations found		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
Animal: 7020	Group: 1	Sex: Female
	Dose: 0	
Necropsy Date: 10/28/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
uterus: fluid filled		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
Animal: 7021	Group: 2	Sex: Male
	Dose: 512	
Necropsy Date: 10/27/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
No observations found		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
Animal: 7022	Group: 2	Sex: Male
	Dose: 512	
Necropsy Date: 10/27/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
No observations found		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
Animal: 7023	Group: 2	Sex: Male
	Dose: 512	
Necropsy Date: 10/27/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
No observations found		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
Animal: 7024	Group: 2	Sex: Male

Individual Animal Necropsy Observations

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---

Dose: 512

Necropsy Date: 10/27/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7025	Group: 2	Sex: Male
	Dose: 512	

Necropsy Date: 10/27/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7026	Group: 2	Sex: Male
	Dose: 512	

Necropsy Date: 10/27/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7027	Group: 2	Sex: Male
	Dose: 512	

Necropsy Date: 10/27/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7028	Group: 2	Sex: Male
	Dose: 512	

Necropsy Date: 10/27/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7029	Group: 2	Sex: Male
	Dose: 512	

Necropsy Date: 10/27/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Individual Animal Necropsy Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

---

Animal: 7030	Group: 2	Sex: Male
	Dose: 512	

---

Necropsy Date: 10/27/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7031	Group: 2	Sex: Female
	Dose: 512	

---

Necropsy Date: 10/28/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7032	Group: 2	Sex: Female
	Dose: 512	

---

Necropsy Date: 10/28/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7033	Group: 2	Sex: Female
	Dose: 512	

---

Necropsy Date: 10/28/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7034	Group: 2	Sex: Female
	Dose: 512	

---

Necropsy Date: 10/28/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7035	Group: 2	Sex: Female
	Dose: 512	

---

Necropsy Date: 10/28/2016

**Last Clinical Observations:**

Alopecia, Left Forelimb, Moderate  
Alopecia, Right Forelimb, Moderate

Individual Animal Necropsy Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

---

**Gross Pathology Observations [Correlation]:**

non correlated finding : no correlated finding {Alopecia, Left Forelimb, Moderate (C) } Alopecia, Right Forelimb, Moderate (C)

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7036	Group:	2	Sex:	Female
		Dose:	512		

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7037	Group:	2	Sex:	Female
		Dose:	512		

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7038	Group:	2	Sex:	Female
		Dose:	512		

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7039	Group:	2	Sex:	Female
		Dose:	512		

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7040	Group:	2	Sex:	Female
		Dose:	512		

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7041	Group:	3	Sex:	Male
		Dose:	1024		

Necropsy Date: 10/27/2016

---

Individual Animal Necropsy Observations

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A 28-Day Dietary Study in Rats

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7042	Group:	3	Sex:	Male
		Dose:	1024		

Necropsy Date: 10/27/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7043	Group:	3	Sex:	Male
		Dose:	1024		

Necropsy Date: 10/27/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7044	Group:	3	Sex:	Male
		Dose:	1024		

Necropsy Date: 10/27/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7045	Group:	3	Sex:	Male
		Dose:	1024		

Necropsy Date: 10/27/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7046	Group:	3	Sex:	Male
		Dose:	1024		

Necropsy Date: 10/27/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7047	Group:	3	Sex:	Male
		Dose:	1024		

Necropsy Date: 10/27/2016

Individual Animal Necropsy Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

**Gross Pathology Observations [Correlation]:**

brain : focal depressed area on left hemisphere. Possible prosection damage

Any remaining protocol required tissues, which have been examined, have no visible lesions

Animal: 7048	Group: 3	Sex: Male
	Dose: 1024	

Necropsy Date: 10/27/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

Animal: 7049	Group: 3	Sex: Male
	Dose: 1024	

Necropsy Date: 10/27/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

Animal: 7050	Group: 3	Sex: Male
	Dose: 1024	

Necropsy Date: 10/27/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

Animal: 7051	Group: 3	Sex: Female
	Dose: 1024	

Necropsy Date: 10/28/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

Animal: 7052	Group: 3	Sex: Female
	Dose: 1024	

Necropsy Date: 10/28/2016

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

Animal: 7053	Group: 3	Sex: Female
	Dose: 1024	



Individual Animal Necropsy Observations

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Necropsy Date: 10/28/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
uterus: fluid filled		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
Animal: 7054	Group: 3	Sex: Female
	Dose: 1024	
Necropsy Date: 10/28/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
No observations found		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
Animal: 7055	Group: 3	Sex: Female
	Dose: 1024	
Necropsy Date: 10/28/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
spleen: stricture		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
Animal: 7056	Group: 3	Sex: Female
	Dose: 1024	
Necropsy Date: 10/28/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
No observations found		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
Animal: 7057	Group: 3	Sex: Female
	Dose: 1024	
Necropsy Date: 10/28/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
No observations found		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
Animal: 7058	Group: 3	Sex: Female
	Dose: 1024	
Necropsy Date: 10/28/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
No observations found		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
Animal: 7059	Group: 3	Sex: Female

Individual Animal Necropsy Observations

PSL Study Number 43166  
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---

	Dose:	1024
Necropsy Date: 10/28/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
No observations found		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
<hr/>		
Animal: 7060	Group: 3	Sex: Female
	Dose: 1024	
Necropsy Date: 10/28/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
No observations found		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
<hr/>		
Animal: 7061	Group: 4	Sex: Male
	Dose: 1536	
Necropsy Date: 10/27/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
No observations found		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
<hr/>		
Animal: 7062	Group: 4	Sex: Male
	Dose: 1536	
Necropsy Date: 10/27/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
No observations found		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
<hr/>		
Animal: 7063	Group: 4	Sex: Male
	Dose: 1536	
Necropsy Date: 10/27/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
No observations found		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
<hr/>		
Animal: 7064	Group: 4	Sex: Male
	Dose: 1536	
Necropsy Date: 10/27/2016		
<b>Gross Pathology Observations [Correlation]:</b>		
No observations found		
Any remaining protocol required tissues, which have been examined, have no visible lesions		
<hr/>		

Individual Animal Necropsy Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

---

Animal: 7065	Group: 4	Sex: Male
	Dose: 1536	

Necropsy Date: 10/27/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7066	Group: 4	Sex: Male
	Dose: 1536	

Necropsy Date: 10/27/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7067	Group: 4	Sex: Male
	Dose: 1536	

Necropsy Date: 10/27/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7068	Group: 4	Sex: Male
	Dose: 1536	

Necropsy Date: 10/27/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7069	Group: 4	Sex: Male
	Dose: 1536	

Necropsy Date: 10/27/2016

---

**Last Clinical Observations:**

Eschar, Head, Superficial

**Gross Pathology Observations [Correlation]:**

non correlated finding : no correlated finding [Eschar, Head, Superficial (C)]

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7070	Group: 4	Sex: Male
	Dose: 1536	

Necropsy Date: 10/27/2016

---

Individual Animal Necropsy Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7071	Group:	4	Sex:	Female
		Dose:	1536		

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7072	Group:	4	Sex:	Female
		Dose:	1536		

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7073	Group:	4	Sex:	Female
		Dose:	1536		

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7074	Group:	4	Sex:	Female
		Dose:	1536		

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7075	Group:	4	Sex:	Female
		Dose:	1536		

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal:	7076	Group:	4	Sex:	Female
		Dose:	1536		

Necropsy Date: 10/28/2016

Individual Animal Necropsy Observations

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7077	Group: 4	Sex: Female
	Dose: 1536	

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7078	Group: 4	Sex: Female
	Dose: 1536	

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7079	Group: 4	Sex: Female
	Dose: 1536	

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

---

Animal: 7080	Group: 4	Sex: Female
	Dose: 1536	

Necropsy Date: 10/28/2016

---

**Gross Pathology Observations [Correlation]:**

No observations found

Any remaining protocol required tissues, which have been examined, have no visible lesions

## **APPENDIX Q: INDIVIDUAL ANIMAL TERMINAL BODY AND ORGAN WEIGHTS<sup>1</sup>**

### **PRODUCT IDENTIFICATION**

Soy Leghemoglobin Preparation

---

<sup>1</sup> Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Individual Animal Terminal Body and Organ Weights

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male		Day(s) Relative to Start Date					
0 mg/kg/day Group 1	Terminal BW (g)	Adrenal Glands Wt (g)	Brain Wt (g)	Epididymides Wt (g)	Heart Wt (g)	Kidneys Wt (g)	Liver Wt (g)
	--	--	--	--	--	--	--
7001	399	0.073	2.19	1.14	1.31	3.19	11.08
7002	359	0.071	2.16	0.94	1.13	2.81	14.06
7003	376	0.071	2.15	0.94	1.19	2.66	12.53
7004	337	0.056	1.98	0.82	1.06	2.26	11.00
7005	329	0.063	2.10	1.04	1.07	2.20	8.44
7006	401	0.066	2.20	1.20	1.30	2.54	11.90
7007	395	0.068	2.13	1.17	1.35	2.83	11.68
7008	355	0.071	2.21	1.04	1.18	2.59	9.44
7009	370	0.062	2.00	0.93	1.11	2.47	9.76
7010	354	0.053	2.29	1.10	1.25	2.86	12.28
Mean	367.5	0.0654	2.141	1.032	1.195	2.641	11.218
SD	25.3	0.0068	0.095	0.123	0.104	0.297	1.657
N	10	10	10	10	10	10	10

Individual Animal Terminal Body and Organ Weights

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Male Day(s) Relative to Start Date

0 mg/kg/day Group 1	Spleen Wt (g)	Testes Wt (g)	Thymus Wt (g)
	--	--	--
7001	0.86	3.65	0.845
7002	0.78	2.18	0.583
7003	0.85	3.27	0.485
7004	0.72	2.43	0.385
7005	0.76	2.91	0.633
7006	0.98	3.12	0.397
7007	1.05	3.96	0.659
7008	0.91	3.34	0.414
7009	0.77	3.23	0.474
7010	0.63	3.39	0.320
Mean	0.831	3.148	0.5205
SD	0.125	0.531	0.1595
N	10	10	10



Individual Animal Terminal Body and Organ Weights

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male		Day(s) Relative to Start Date					
512 mg/kg/day Group 2	Terminal BW (g)	Adrenal Glands Wt (g)	Bran Wt (g)	Epididymides Wt (g)	Heart Wt (g)	Kidneys Wt (g)	Liver Wt (g)
	--	--	--	--	--	--	--
7021	363	0.076	1.96	1.17	1.14	2.68	11.05
7022	374	0.074	2.21	1.10	1.28	3.01	11.54
7023	386	0.054	2.22	1.19	1.29	2.47	10.80
7024	374	0.067	2.31	1.08	1.28	2.57	10.74
7025	362	0.069	2.09	1.05	1.12	2.42	10.75
7026	378	0.053	2.17	1.17	1.26	2.86	12.25
7027	366	0.087	2.15	1.01	1.28	2.65	10.57
7028	336	0.058	2.14	1.06	1.13	2.67	10.68
7029	428	0.062	2.21	0.92	1.54	3.01	12.52
7030	358	0.055	1.97	1.13	1.22	2.44	10.92
Mean	372.5	0.0655	2.143	1.088	1.254	2.678	11.182
SD	23.8	0.0112	0.110	0.083	0.121	0.219	0.691
N	10	10	10	10	10	10	10

Individual Animal Terminal Body and Organ Weights

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Male Day(s) Relative to Start Date

5f2 mg/kg/day Group 2	Spleen Wt (g)	Testes Wt (g)	Thymus Wt (g)
	--	--	--
7021	0.80	3.39	0.359
7022	0.84	3.09	0.623
7023	0.78	2.95	0.521
7024	0.73	3.39	0.639
7025	0.86	3.16	0.406
7026	0.92	3.96	0.648
7027	0.68	3.42	0.715
7028	1.04	3.63	0.614
7029	0.72	3.56	0.643
7030	0.76	3.26	0.493
Mean	0.813	3.381	0.5661
SD	0.107	0.292	0.1162
N	10	10	10

Individual Animal Terminal Body and Organ Weights

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male		Day(s) Relative to Start Date					
1024 mg/kg/day Group 3	Terminal BW (g)	Adrenal Glands Wt (g)	Brain Wt (g)	Epididymides Wt (g)	Heart Wt (g)	Kidneys Wt (g)	Liver Wt (g)
	--	--	--	--	--	--	--
7041	375	0.068	2.20	1.14	1.15	2.89	13.47
7042	421	0.074	2.29	1.07	1.38	2.91	13.21
7043	355	0.056	2.14	0.93	1.21	2.50	10.42
7044	406	0.067	2.33	1.35	1.36	2.96	13.78
7045	377	0.064	2.25	0.94	1.27	2.45	11.88
7046	418	0.080	2.27	0.96	1.46	3.11	13.24
7047	404	0.046	1.87	0.98	1.30	2.79	12.54
7048	413	0.066	2.31	1.06	1.32	3.10	15.05
7049	328	0.035	2.12	0.93	1.13	2.51	9.59
7050	343	0.057	2.08	0.99	1.14	2.67	9.99
Mean	384.0	0.0593	2.186	1.035	1.272	2.789	12.317
SD	33.4	0.0116	0.140	0.131	0.113	0.246	1.804
N	10	10	10	10	10	10	10

Individual Animal Terminal Body and Organ Weights

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Male Day(s) Relative to Start Date

1024 mg/kg/day Group 3	Spleen Wt (g)	Testes Wt (g)	Thymus Wt (g)
	--	--	--
7041	0.82	3.57	0.513
7042	0.78	2.99	0.534
7043	0.77	3.43	0.441
7044	0.75	3.76	0.502
7045	0.68	3.30	0.559
7046	0.82	3.15	0.841
7047	0.83	3.12	0.552
7048	0.78	3.18	0.612
7049	0.78	3.16	0.409
7050	0.68	3.00	0.503
Mean	0.769	3.266	0.5466
SD	0.053	0.251	0.1185
N	10	10	10

Individual Animal Terminal Body and Organ Weights

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male		Day(s) Relative to Start Date					
t536 mg/kg/day Group 4	Terminal BW (g)	Adrenal Glands Wt (g)	Brain Wt (g)	Epididymides Wt (g)	Heart Wt (g)	Kidneys Wt (g)	Liver Wt (g)
	--	--	--	--	--	--	--
7061	381	0.064	2.09	1.04	1.22	2.61	10.92
7062	379	0.058	2.14	0.88	1.26	2.83	10.89
7063	353	0.063	1.99	1.13	1.08	2.78	12.40
7064	413	0.064	2.27	0.87	1.29	3.05	12.47
7065	405	0.075	2.24	0.91	1.36	3.21	13.51
7066	394	0.069	2.15	1.10	1.29	2.77	14.23
7067	389	0.073	2.10	1.05	1.13	2.48	11.20
7068	361	0.084	2.22	1.12	1.20	2.77	12.87
7069	350	0.049	2.02	0.94	1.12	2.48	9.43
7070	368	0.073	2.30	1.04	1.24	3.02	13.01
Mean	379.3	0.0672	2.152	1.008	1.219	2.800	12.093
SD	21.4	0.0098	0.105	0.100	0.088	0.241	1.452
N	10	10	10	10	10	10	10

Individual Animal Terminal Body and Organ Weights

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Male		Day(s) Relative to Start Date		
1536 mg/kg/day Group 4	Spleen Wt (g)	Testes Wt (g)	Thymus Wt (g)	
	--	--	--	
7061	0.82	3.22	0.476	
7062	0.77	3.00	0.386	
7063	0.87	3.25	0.510	
7064	0.86	3.66	0.437	
7065	0.82	3.25	0.715	
7066	0.75	3.00	0.548	
7067	0.73	2.99	0.549	
7068	1.01	3.56	0.702	
7069	0.61	3.55	0.461	
7070	0.85	3.24	0.512	
Mean	0.809	3.272	0.5276	
SD	0.105	0.246	0.1097	
N	10	10	10	

Individual Animal Terminal Body and Organ Weights

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female		Day(s) Relative to Start Date					
0 mg/kg/day Group 1	Terminal BW (g)	Adrenal Glands Wt (g)	Brain Wt (g)	Heart Wt (g)	Kidneys Wt (g)	Liver Wt (g)	Ovaries with Oviducts Wt (g)
	7011	194	0.061	1.83	0.73	1.59	6.61
7012	206	0.075	1.94	0.74	1.68	6.20	0.128
7013	266	0.084	2.14	1.00	2.07	7.83	0.152
7014	227	0.076	2.09	0.90	1.83	6.79	0.145
7015	236	0.069	2.08	0.90	1.65	7.32	0.139
7016	227	0.068	1.94	0.83	1.68	8.19	0.124
7017	205	0.067	1.94	0.71	1.50	6.05	0.104
7018	241	0.070	2.02	0.91	1.85	7.23	0.156
7019	240	0.079	2.05	0.85	1.86	7.74	0.108
7020	250	0.068	2.04	0.83	1.81	7.60	0.129
Mean	229.2	0.0717	2.007	0.840	1.752	7.156	0.1309
SD	22.3	0.0067	0.093	0.092	0.164	0.720	0.0173
N	10	10	10	10	10	10	10

Individual Animal Terminal Body and Organ Weights

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Female		Day(s) Relative to Start Date		
0 mg/kg/day Group 1	Spleen Wt (g)	Thymus Wt (g)	Uterus Wt (g)	
		-	-	-
7011	0.39	0.369	0.57	
7012	0.42	0.258	0.60	
7013	0.60	0.480	0.96	
7014	0.49	0.460	0.65	
7015	0.42	0.491	0.56	
7016	0.56	0.481	0.48	
7017	0.47	0.385	0.87	
7018	0.53	0.373	0.97	
7019	0.66	0.413	0.44	
7020	0.44	0.633	1.17	
Mean	0.498	0.4343	0.727	
SD	0.088	0.0998	0.247	
N	10	10	10	



Individual Animal Terminal Body and Organ Weights

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female		Day(s) Relative to Start Date					
512 mg/kg/day Group 2	Terminal BW (g)	Adrenal Glands Wt (g)	Brain Wt (g)	Heart Wt (g)	Kidneys Wt (g)	Liver Wt (g)	Ovaries with Oviducts Wt (g)
		-	-	-	-	-	-
7031	234	0.072	2.02	0.88	1.88	7.87	0.118
7032	216	0.074	2.05	0.80	1.91	7.42	0.119
7033	217	0.085	2.01	0.79	1.95	7.54	0.141
7034	199	0.061	1.92	0.75	1.61	6.34	0.113
7035	233	0.068	1.92	0.85	1.61	7.63	0.142
7036	228	0.063	1.86	0.82	1.76	8.83	0.129
7037	182	0.059	1.88	0.75	1.57	5.93	0.096
7038	247	0.083	1.88	0.87	1.83	7.05	0.133
7039	243	0.070	2.16	0.87	2.00	8.62	0.124
7040	257	0.078	2.06	0.92	2.08	9.13	0.157
Mean	225.6	0.0713	1.976	0.830	1.820	7.636	0.1272
SD	22.7	0.0089	0.099	0.057	0.177	1.037	0.0172
N	10	10	10	10	10	10	10

Individual Animal Terminal Body and Organ Weights

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Female	Day(s) Relative to Start Date		
512 mg/kg/day Group 2	Spleen Wt (g)	Thymus Wt (g)	Uterus Wt (g)
	7031	0.61	0.473
7032	0.43	0.446	0.54
7033	0.54	0.532	0.54
7034	0.39	0.492	0.41
7035	0.43	0.411	0.38
7036	0.60	0.480	0.43
7037	0.39	0.370	0.54
7038	0.44	0.625	0.45
7039	0.61	0.396	0.41
7040	0.74	0.429	0.41
Mean	0.518	0.4654	0.457
SD	0.119	0.0741	0.061
N	10	10	10

Individual Animal Terminal Body and Organ Weights

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female		Day(s) Relative to Start Date					
1024 mg/kg/day Group 3	Terminal BW (g)	Adrenal Glands Wt (g)	Brain Wt (g)	Heart Wt (g)	Kidneys Wt (g)	Liver Wt (g)	Ovaries with Oviducts Wt (g)
	7051	217	0.056	2.14	0.82	1.71	7.05
7052	227	0.067	1.94	0.83	1.81	8.34	0.108
7053	247	0.061	2.07	0.85	1.62	7.54	0.116
7054	246	0.077	2.01	0.86	1.52	7.11	0.122
7055	257	0.065	2.03	0.92	1.98	7.85	0.140
7056	250	0.066	2.11	0.81	1.81	7.24	0.107
7057	222	0.051	1.97	0.82	1.75	7.31	0.134
7058	224	0.065	2.07	0.86	1.70	6.82	0.105
7059	248	0.077	1.96	0.89	1.94	6.57	0.144
7060	225	0.079	2.16	0.84	1.85	7.55	0.121
Mean	236.3	0.0664	2.046	0.850	1.769	7.338	0.1231
SD	14.5	0.0092	0.077	0.034	0.140	0.512	0.0143
N	10	10	10	10	10	10	10

Individual Animal Terminal Body and Organ Weights

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Female		Day(s) Relative to Start Date		
1024 mg/kg/day Group 3	Spleen Wt (g)	Thymus Wt (g)	Uterus Wt (g)	
7051	0.55	0.395	0.46	
7052	0.48	0.581	0.43	
7053	0.53	0.445	1.29	
7054	0.51	0.339	0.54	
7055	0.48	0.534	0.63	
7056	0.62	0.635	0.45	
7057	0.56	0.531	0.49	
7058	0.45	0.363	0.43	
7059	0.52	0.435	0.90	
7060	0.37	0.504	0.53	
Mean	0.507	0.4762	0.615	
SD	0.068	0.0967	0.276	
N	10	10	10	

Individual Animal Terminal Body and Organ Weights

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female		Day(s) Relative to Start Date					
1536 mg/kg/day Group 4	Terminal BW (g)	Adrenal Glands Wt (g)	Brain Wt (g)	Heart Wt (g)	Kidneys Wt (g)	Liver Wt (g)	Ovaries with Oviducts Wt (g)
	7071	235	0.065	2.03	0.81	1.77	8.18
7072	232	0.074	2.02	0.85	1.87	7.67	0.142
7073	244	0.073	1.94	0.91	1.72	7.76	0.140
7074	221	0.064	2.08	0.78	1.90	7.15	0.105
7075	225	0.077	2.05	0.81	1.80	8.84	0.145
7076	234	0.080	2.02	0.82	2.02	8.32	0.145
7077	255	0.064	2.05	0.89	1.87	7.75	0.126
7078	222	0.082	1.93	0.83	1.79	7.09	0.129
7079	248	0.092	2.04	0.99	1.70	7.39	0.160
7080	222	0.066	2.05	0.79	1.71	7.48	0.128
Mean	233.8	0.0737	2.021	0.848	1.815	7.763	0.1364
SD	11.9	0.0093	0.049	0.065	0.101	0.548	0.0150
N	10	10	10	10	10	10	10

Individual Animal Terminal Body and Organ Weights

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female		Day(s) Relative to Start Date		
1536 mg/kg/day Group 4	Spleen Wt (g)	Thymus Wt (g)	Uterus Wt (g)	
	7071	0.60	0.643	0.46
7072	0.54	0.459	0.52	
7073	0.51	0.379	0.52	
7074	0.39	0.379	0.52	
7075	0.48	0.440	0.50	
7076	0.53	0.665	0.49	
7077	0.54	0.616	0.38	
7078	0.49	0.584	0.41	
7079	0.58	0.440	0.56	
7080	0.47	0.613	0.54	
Mean	0.513	0.5218	0.490	
SD	0.060	0.1127	0.057	
N	10	10	10	

## APPENDIX R: INDIVIDUAL ANIMAL ORGAN-TO-BODY WEIGHT RATIOS<sup>1</sup>

### PRODUCT IDENTIFICATION

Soy Leghemoglobin Preparation

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<sup>1</sup> Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.

Individual Animal Organ-to-Body Weight Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male		Day(s) Relative to Start Date					
0 mg/kg/day Group 1	Adrenal /TBW (Ratio)	Brain /TBW (Ratio)	Epididymides /TBW (Ratio)	Heart /TBW (Ratio)	Kidneys /TBW (Ratio)	Liver /TBW (Ratio)	Spleen /TBW (Ratio)
	7001	0.183	5.49	2.857	3.28	7.99	27.77
7002	0.198	6.02	2.618	3.15	7.83	39.16	2.17
7003	0.189	5.72	2.500	3.16	7.07	33.32	2.26
7004	0.166	5.88	2.433	3.15	6.71	32.64	2.14
7005	0.191	6.38	3.161	3.25	6.69	25.65	2.31
7006	0.165	5.49	2.993	3.24	6.33	29.68	2.44
7007	0.172	5.39	2.962	3.42	7.16	29.57	2.66
7008	0.200	6.23	2.930	3.32	7.30	26.59	2.56
7009	0.168	5.41	2.514	3.00	6.68	26.38	2.08
7010	0.150	6.47	3.107	3.53	8.08	34.72	1.78
Mean	0.1781	5.846	2.8075	3.251	7.184	30.549	2.256
SD	0.0165	0.411	0.2682	0.151	0.610	4.348	0.255
N	10	10	10	10	10	10	10



Individual Animal Organ-to-Body Weight Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Day(s) Relative to Start Date

0 mg/kg/day Group 1	Testes /TBW (Ratio)	Thymus /TBW (Ratio)
7001	9.15	2.118
7002	6.07	1.624
7003	8.70	1.316
7004	7.21	1.142
7005	8.84	1.924
7006	7.78	0.990
7007	10.03	1.668
7008	9.41	1.166
7009	8.73	1.281
7010	9.58	0.904
Mean	8.549	1.4134
SD	1.201	0.4037
N	10	10

## Individual Animal Organ-to-Body Weight Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Day(s) Relative to Start Date

512 mg/kg/day Group 2	Adrenal /TBW (Ratio)	Brain /TBW (Ratio)	Epididymides /TBW (Ratio)	Heart /TBW (Ratio)	Kidneys /TBW (Ratio)	Liver /TBW (Ratio)	Spleen /TBW (Ratio)
	-	-	-	-	-	-	-
7021	0.209	5.40	3.223	3.14	7.38	30.44	2.20
7022	0.198	5.91	2.941	3.42	8.05	30.86	2.25
7023	0.140	5.75	3.083	3.34	6.40	27.98	2.02
7024	0.179	6.18	2.888	3.42	6.87	28.72	1.95
7025	0.191	5.77	2.901	3.09	6.69	29.70	2.38
7026	0.140	5.74	3.095	3.33	7.57	32.41	2.43
7027	0.238	5.87	2.760	3.50	7.24	28.88	1.86
7028	0.173	6.37	3.155	3.36	7.95	31.79	3.10
7029	0.145	5.16	2.150	3.60	7.03	29.25	1.68
7030	0.154	5.50	3.156	3.41	6.82	30.50	2.12
Mean	0.1766	5.766	2.9351	3.362	7.199	30.052	2.199
SD	0.0328	0.355	0.3125	0.151	0.541	1.405	0.391
N	10	10	10	10	10	10	10

Individual Animal Organ-to-Body Weight Ratios

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Male Day(s) Relative to Start Date

512 mg/kg/day Group 2	Testes /TBW (Ratio)	Thymus /TBW (Ratio)
	7021	9.34
7022	8.26	1.666
7023	7.64	1.350
7024	9.06	1.709
7025	8.73	1.122
7026	10.48	1.714
7027	9.34	1.954
7028	10.80	1.827
7029	8.32	1.502
7030	9.11	1.377
Mean	9.108	1.5209
SD	0.971	0.3105
N	10	10

Individual Animal Organ-to-Body Weight Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male		Day(s) Relative to Start Date					
1024 mg/kg/day Group 3	Adrenal /TBW (Ratio)	Brain /TBW (Ratio)	Epididymides /TBW (Ratio)	Heart /TBW (Ratio)	Kidneys /TBW (Ratio)	Liver /TBW (Ratio)	Spleen /TBW (Ratio)
	7041	0.181	5.87	3.040	3.07	7.71	35.92
7042	0.176	5.44	2.542	3.28	6.91	31.38	1.85
7043	0.158	6.03	2.620	3.41	7.04	29.35	2.17
7044	0.165	5.74	3.325	3.35	7.29	33.94	1.85
7045	0.170	5.97	2.493	3.37	6.50	31.51	1.80
7046	0.144	5.43	2.297	3.49	7.44	31.67	1.96
7047	0.114	4.63	2.426	3.22	6.91	31.04	2.05
7048	0.160	5.59	2.567	3.20	7.51	36.44	1.89
7049	0.107	6.46	2.835	3.45	7.65	29.24	2.38
7050	0.166	6.06	2.866	3.32	7.78	29.13	1.98
Mean	0.1540	5.722	2.7030	3.315	7.274	31.962	2.012
SD	0.0253	0.497	0.3143	0.128	0.421	2.654	0.184
N	10	10	10	10	10	10	10

Individual Animal Organ-to-Body Weight Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male Day(s) Relative to Start Date

1024 mg/kg/day Group 3	Testes /TBW (Ratio)	Thymus /TBW (Ratio)
7041	9.52	1.368
7042	7.10	1.268
7043	9.66	1.242
7044	9.26	1.236
7045	8.75	1.483
7046	7.54	2.012
7047	7.72	1.366
7048	7.70	1.482
7049	9.63	1.247
7050	8.75	1.466
Mean	8.564	1.4171
SD	0.970	0.2319
N	10	10

Individual Animal Organ-to-Body Weight Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male		Day(s) Relative to Start Date					
1536 mg/kg/day Group 4	Adrenal /TBW (Ratio)	Brain /TBW (Ratio)	Epididymides /TBW (Ratio)	Heart /TBW (Ratio)	Kidneys /TBW (Ratio)	Liver /TBW (Ratio)	Spleen /TBW (Ratio)
	7061	0.168	5.49	2.730	3.20	6.85	28.66
7062	0.153	5.65	2.322	3.32	7.47	28.73	2.03
7063	0.178	5.64	3.201	3.06	7.88	35.13	2.46
7064	0.155	5.50	2.107	3.12	7.38	30.19	2.08
7065	0.185	5.53	2.247	3.36	7.93	33.36	2.02
7066	0.175	5.46	2.792	3.27	7.03	36.12	1.90
7067	0.188	5.40	2.699	2.90	6.38	28.79	1.88
7068	0.233	6.15	3.102	3.32	7.67	35.65	2.80
7069	0.140	5.77	2.686	3.20	7.09	26.94	1.74
7070	0.198	6.25	2.826	3.37	8.21	35.35	2.31
Mean	0.1773	5.682	2.6712	3.214	7.387	31.893	2.139
SD	0.0264	0.294	0.3544	0.149	0.560	3.559	0.312
N	10	10	10	10	10	10	10

Individual Animal Organ-to-Body Weight Ratios

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Male	Day(s) Relative to Start Date	
1536 mg/kg/day Group 4	Testes /TBW (Ratio)	Thymus /TBW (Ratio)
7061	8.45	1.249
7062	7.92	0.966
7063	9.21	1.445
7064	8.86	1.058
7065	8.02	1.765
7066	7.61	1.391
7067	7.69	1.411
7068	9.86	1.945
7069	10.14	1.317
7070	8.80	1.391
Mean	8.657	1.3939
SD	0.885	0.2919
N	10	10

Individual Animal Organ-to-Body Weight Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female		Day(s) Relative to Start Date					
0 mg/kg/day Group 1	Adrenal /TBW (Ratio)	Brain /TBW (Ratio)	Heart /TBW (Ratio)	Kidneys /TBW (Ratio)	Liver /TBW (Ratio)	Ovaries with oviducts/TBW (Ratio)	Spleen /TBW (Ratio)
	7011	0.314	9.43	3.76	8.20	34.07	0.639
7012	0.364	9.42	3.59	8.16	30.10	0.621	2.04
7013	0.316	8.05	3.76	7.78	29.44	0.571	2.26
7014	0.335	9.21	3.96	8.06	29.91	0.639	2.16
7015	0.292	8.81	3.81	6.99	31.02	0.589	1.78
7016	0.300	8.55	3.66	7.40	36.08	0.546	2.47
7017	0.327	9.46	3.46	7.32	29.51	0.507	2.29
7018	0.290	8.38	3.78	7.68	30.00	0.647	2.20
7019	0.329	8.54	3.54	7.75	32.25	0.450	2.75
7020	0.272	8.16	3.32	7.24	30.40	0.516	1.76
Mean	0.3139	8.801	3.665	7.657	31.278	0.5727	2.171
SD	0.0265	0.545	0.189	0.412	2.212	0.0669	0.300
N	10	10	10	10	10	10	10



Individual Animal Organ-to-Body Weight Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

0 mg/kg/day Group 1	Thymus /TBW (Ratio)	Uterus /TBW (Ratio)
	-	-
7011	1.902	2.94
7012	1.252	2.91
7013	1.805	3.61
7014	2.026	2.86
7015	2.081	2.37
7016	2.119	2.11
7017	1.878	4.24
7018	1.548	4.02
7019	1.721	1.83
7020	2.532	4.68
Mean	1.8863	3.159
SD	0.3463	0.949
N	10	10

Individual Animal Organ-to-Body Weight Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female		Day(s) Relative to Start Date					
512 mg/kg/day Group 2	Adrenal /TBW (Ratio)	Brain /TBW (Ratio)	Heart /TBW (Ratio)	Kidneys /TBW (Ratio)	Liver /TBW (Ratio)	Ovaries with oviducts/TBW (Ratio)	Spleen /TBW (Ratio)
	7031	0.308	8.63	3.76	8.03	33.63	0.504
7032	0.343	9.49	3.70	8.84	34.35	0.551	1.99
7033	0.392	9.26	3.64	8.99	34.75	0.650	2.49
7034	0.307	9.65	3.77	8.09	31.86	0.568	1.96
7035	0.292	8.24	3.65	6.91	32.75	0.609	1.85
7036	0.276	8.16	3.60	7.72	38.73	0.566	2.63
7037	0.324	10.33	4.12	8.63	32.58	0.527	2.14
7038	0.336	7.61	3.52	7.41	28.54	0.538	1.78
7039	0.288	8.89	3.58	8.23	35.47	0.510	2.51
7040	0.304	8.02	3.58	8.09	35.53	0.611	2.88
Mean	0.3168	8.828	3.692	8.094	33.819	0.5635	2.284
SD	0.0336	0.852	0.171	0.639	2.693	0.0474	0.384
N	10	10	10	10	10	10	10

Individual Animal Organ-to-Body Weight Ratios

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

512 mg/kg/day Group 2	Thymus /TBW (Ratio)	Uterus /TBW (Ratio)
7031	2.021	1.97
7032	2.065	2.50
7033	2.452	2.49
7034	2.472	2.06
7035	1.764	1.63
7036	2.105	1.89
7037	2.033	2.97
7038	2.530	1.82
7039	1.630	1.69
7040	1.669	1.60
Mean	2.0742	2.060
SD	0.3287	0.452
N	10	10

Individual Animal Organ-to-Body Weight Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female		Day(s) Relative to Start Date					
1024 mg/kg/day Group 3	Adrenal /TBW (Ratio)	Brain /TBW (Ratio)	Heart /TBW (Ratio)	Kidneys /TBW (Ratio)	Liver /TBW (Ratio)	Ovaries with oviducts/TBW (Ratio)	Spleen /TBW (Ratio)
	7051	0.258	9.86	3.78	7.88	32.49	0.618
7052	0.295	8.55	3.66	7.97	36.74	0.476	2.11
7053	0.247	8.38	3.44	6.56	30.53	0.470	2.15
7054	0.313	8.17	3.50	6.18	28.90	0.496	2.07
7055	0.253	7.90	3.58	7.70	30.54	0.545	1.87
7056	0.264	8.44	3.24	7.24	28.96	0.428	2.48
7057	0.230	8.87	3.69	7.88	32.93	0.604	2.52
7058	0.290	9.24	3.84	7.59	30.45	0.469	2.01
7059	0.310	7.90	3.59	7.82	26.49	0.581	2.10
7060	0.351	9.60	3.73	8.22	33.56	0.538	1.64
Mean	0.2812	8.692	3.605	7.505	31.158	0.5222	2.149
SD	0.0372	0.686	0.178	0.657	2.883	0.0643	0.291
N	10	10	10	10	10	10	10

Individual Animal Organ-to-Body Weight Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

1024 mg/kg/day Group 3	Thymus /TBW (Ratio)	Uterus /TBW (Ratio)
	-	-
7051	1.820	2.12
7052	2.559	1.89
7053	1.802	5.22
7054	1.378	2.20
7055	2.078	2.45
7056	2.540	1.80
7057	2.392	2.21
7058	1.621	1.92
7059	1.754	3.63
7060	2.240	2.36
Mean	2.0184	2.579
SD	0.4057	1.063
N	10	10

Individual Animal Organ-to-Body Weight Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

1536 mg/kg/day Group 4	Adrenal /TBW (Ratio)	Brain /TBW (Ratio)	Heart /TBW (Ratio)	Kidneys /TBW (Ratio)	Liver /TBW (Ratio)	Ovaries with oviducts/TBW (Ratio)	Spleen /TBW (Ratio)
7071	0.277	8.64	3.45	7.53	34.81	0.613	2.55
7072	0.319	8.71	3.66	8.06	33.06	0.612	2.33
7073	0.299	7.95	3.73	7.05	31.80	0.574	2.09
7074	0.290	9.41	3.53	8.60	32.35	0.475	1.76
7075	0.342	9.11	3.60	8.00	39.29	0.644	2.13
7076	0.342	8.63	3.50	8.63	35.56	0.620	2.26
7077	0.251	8.04	3.49	7.33	30.39	0.494	2.12
7078	0.369	8.69	3.74	8.06	31.94	0.581	2.21
7079	0.371	8.23	3.99	6.85	29.80	0.645	2.34
7080	0.297	9.23	3.56	7.70	33.69	0.577	2.12
Mean	0.3157	8.664	3.625	7.783	33.269	0.5835	2.191
SD	0.0399	0.492	0.163	0.602	2.772	0.0581	0.206
N	10	10	10	10	10	10	10

Individual Animal Organ-to-Body Weight Ratios

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Female Day(s) Relative to Start Date

1536 mg/kg/day Group 4	Thymus /TBW (Ratio)	Uterus /TBW (Ratio)
7071	2.736	1.96
7072	1.978	2.24
7073	1.553	2.13
7074	1.715	2.35
7075	1.956	2.22
7076	2.842	2.09
7077	2.416	1.49
7078	2.631	1.85
7079	1.774	2.26
7080	2.761	2.43
Mean	2.2362	2.103
SD	0.4918	0.277
N	10	10

## APPENDIX S: INDIVIDUAL ANIMAL ORGAN-TO-BRAIN WEIGHT RATIOS<sup>1,2</sup>

### PRODUCT IDENTIFICATION

Soy Leghemoglobin Preparation

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<sup>1</sup> [organ weight/brain weight]

<sup>2</sup> Group 2: 512 mg/kg/day of test substance corresponds to 250 mg/kg/day of the active ingredient.  
Group 3: 1024 mg/kg/day of test substance corresponds to 500 mg/kg/day of the active ingredient.  
Group 4: 1536 mg/kg/day of test substance corresponds to 750 mg/kg/day of the active ingredient.



Individual Animal Organ-to-Brain Weight Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male		Day(s) Relative to Start Date					
0 mg/kg/day Group 1	Adrenal /BrW (Ratio)	Epididymides /BrW (Ratio)	Heart /BrW (Ratio)	Kidneys /BrW (Ratio)	Liver /BrW (Ratio)	Spleen /BrW (Ratio)	Testes /BrW (Ratio)
		-	-	-	-	-	-
7001	0.033	0.521	0.60	1.46	5.06	0.39	1.67
7002	0.033	0.435	0.52	1.30	6.51	0.36	1.01
7003	0.033	0.437	0.55	1.24	5.83	0.40	1.52
7004	0.028	0.414	0.54	1.14	5.56	0.38	1.23
7005	0.030	0.495	0.51	1.05	4.02	0.36	1.39
7006	0.030	0.545	0.59	1.15	5.41	0.45	1.42
7007	0.032	0.549	0.63	1.33	5.48	0.49	1.86
7008	0.032	0.471	0.53	1.17	4.27	0.41	1.51
7009	0.031	0.465	0.56	1.24	4.88	0.39	1.62
7010	0.023	0.480	0.55	1.25	5.37	0.28	1.48
Mean	0.0306	0.4813	0.558	1.232	5.238	0.388	1.469
SD	0.0031	0.0465	0.038	0.114	0.727	0.057	0.235
N	10	10	10	10	10	10	10

Individual Animal Organ-to-Brain Weight Ratios  
 PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Male	Day(s) Relative to Start Date	Thymus B/W (Ratio)
0		
mg/kg/day Group 1		
	7001	0.386
	7002	0.270
	7003	0.230
	7004	0.194
	7005	0.301
	7006	0.180
	7007	0.309
	7008	0.187
	7009	0.237
	7010	0.140
Mean		0.2436
SD		0.0739
N		10

Individual Animal Organ-to-Brain Weight Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male		Day(s) Relative to Start Date					
512 mg/kg/day Group 2	Adrenal /BrW (Ratio)	Epididymides /BrW (Ratio)	Heart /BrW (Ratio)	Kidneys /BrW (Ratio)	Liver /BrW (Ratio)	Spleen /BrW (Ratio)	Testes /BrW (Ratio)
	7021	0.039	0.597	0.58	1.37	5.64	0.41
7022	0.033	0.498	0.58	1.36	5.22	0.38	1.40
7023	0.024	0.536	0.58	1.11	4.86	0.35	1.33
7024	0.029	0.468	0.55	1.11	4.65	0.32	1.47
7025	0.033	0.502	0.54	1.16	5.14	0.41	1.51
7026	0.024	0.539	0.58	1.32	5.65	0.42	1.82
7027	0.040	0.470	0.60	1.23	4.92	0.32	1.59
7028	0.027	0.495	0.53	1.25	4.99	0.49	1.70
7029	0.028	0.416	0.70	1.36	5.67	0.33	1.61
7030	0.028	0.574	0.62	1.24	5.54	0.39	1.65
Mean	0.0307	0.5095	0.585	1.251	5.228	0.380	1.581
SD	0.0056	0.0535	0.048	0.100	0.374	0.055	0.155
N	10	10	10	10	10	10	10

Individual Animal Organ-to-Brain Weight Ratios

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Male	Day(s) Relative to Start Date	
512 mg/kg/day Group 2		Thymus /BrW (Ratio)
		-
	7021	0.183
	7022	0.282
	7023	0.235
	7024	0.277
	7025	0.194
	7026	0.299
	7027	0.333
	7028	0.287
7029	0.291	
7030	0.250	
Mean	0.2630	
SD	0.0472	
N	10	

Individual Animal Organ-to-Brain Weight Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male		Day(s) Relative to Start Date					
1024 mg/kg/day Group 3	Adrenal /BrW (Ratio)	Epididymides /BrW (Ratio)	Heart /BrW (Ratio)	Kidneys /BrW (Ratio)	Liver /BrW (Ratio)	Spleen /BrW (Ratio)	Testes /BrW (Ratio)
	7041	0.031	0.518	0.52	1.31	6.12	0.37
7042	0.032	0.467	0.60	1.27	5.77	0.34	1.31
7043	0.026	0.435	0.57	1.17	4.87	0.36	1.60
7044	0.029	0.579	0.58	1.27	5.91	0.32	1.61
7045	0.028	0.418	0.56	1.09	5.28	0.30	1.47
7046	0.026	0.423	0.64	1.37	5.83	0.36	1.39
7047	0.025	0.524	0.70	1.49	6.71	0.44	1.67
7048	0.029	0.459	0.57	1.34	6.52	0.34	1.38
7049	0.017	0.439	0.53	1.18	4.52	0.37	1.49
7050	0.027	0.476	0.55	1.28	4.80	0.33	1.44
Mean	0.0270	0.4738	0.583	1.278	5.633	0.353	1.498
SD	0.0043	0.0521	0.052	0.114	0.740	0.039	0.123
N	10	10	10	10	10	10	10

Individual Animal Organ-to-Brain Weight Ratios

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Male	Day(s) Relative to Start Date	
1024 mg/kg/day Group 3		Thymus /BW (Ratio)
		-
	7041	0.233
	7042	0.233
	7043	0.206
	7044	0.215
	7045	0.248
	7046	0.370
	7047	0.295
	7048	0.265
	7049	0.193
	7050	0.242
	Mean	0.2502
	SD	0.0514
	N	10

Individual Animal Organ-to-Brain Weight Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Male		Day(s) Relative to Start Date					
1536 mg/kg/day Group 4	Adrenal /BrW (Ratio)	Epididymides /BrW (Ratio)	Heart /BrW (Ratio)	Kidneys /BrW (Ratio)	Liver /BrW (Ratio)	Spleen /BrW (Ratio)	Testes /BrW (Ratio)
7061	0.031	0.498	0.58	1.25	5.22	0.39	1.54
7062	0.027	0.411	0.59	1.32	5.09	0.36	1.40
7063	0.032	0.568	0.54	1.40	6.23	0.44	1.63
7064	0.028	0.383	0.57	1.34	5.49	0.38	1.61
7065	0.033	0.406	0.61	1.43	6.03	0.37	1.45
7066	0.032	0.512	0.60	1.29	6.62	0.35	1.40
7067	0.035	0.500	0.54	1.18	5.33	0.35	1.42
7068	0.038	0.505	0.54	1.25	5.80	0.45	1.60
7069	0.024	0.465	0.55	1.23	4.67	0.30	1.76
7070	0.032	0.452	0.54	1.31	5.66	0.37	1.41
Mean	0.0312	0.4700	0.566	1.300	5.614	0.376	1.523
SD	0.0039	0.0573	0.027	0.078	0.579	0.044	0.125
N	10	10	10	10	10	10	10

Individual Animal Organ-to-Brain Weight Ratios

PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Male	Day(s) Relative to Start Date
1536 mg/kg/day Group 4	Thymus /BrW (Ratio)
7061	0.228
7062	0.171
7063	0.256
7064	0.193
7065	0.319
7066	0.255
7067	0.261
7068	0.316
7069	0.228
7070	0.223
Mean	0.2450
SD	0.0476
N	10



Individual Animal Organ-to-Brain Weigh Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female		Day(s) Relative to Start Date					
0 mg/kg/day Group 1	Adrenal /BrW (Ratio)	Heart /BrW (Ratio)	Kidneys /BrW (Ratio)	Liver /BrW (Ratio)	Ovaries with oviducts/BrW (Ratio)	Spleen /BrW (Ratio)	Thymus /BrW (Ratio)
		-	-	-	-	-	-
7011	0.033	0.40	0.87	3.61	0.068	0.21	0.202
7012	0.039	0.38	0.87	3.20	0.066	0.22	0.133
7013	0.039	0.47	0.97	3.66	0.071	0.28	0.224
7014	0.036	0.43	0.88	3.25	0.069	0.23	0.220
7015	0.033	0.43	0.79	3.52	0.067	0.20	0.236
7016	0.035	0.43	0.87	4.22	0.064	0.29	0.248
7017	0.035	0.37	0.77	3.12	0.054	0.24	0.198
7018	0.035	0.45	0.92	3.58	0.077	0.26	0.185
7019	0.039	0.41	0.91	3.78	0.053	0.32	0.201
7020	0.033	0.41	0.89	3.73	0.063	0.22	0.310
Mean	0.0357	0.418	0.872	3.566	0.0652	0.248	0.2158
SD	0.0024	0.031	0.056	0.325	0.0075	0.039	0.0459
N	10	10	10	10	10	10	10

Individual Animal Organ-to-Brain Weight Ratios  
 PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex	Female	Day(s) Relative to Start, Date	Uterus /Brain (Ratio)
0			
	mg/kg/day Group 1		
		7011	0.31
		7012	0.31
		7013	0.45
		7014	0.31
		7015	0.27
		7016	0.25
		7017	0.45
		7018	0.48
		7019	0.21
		7020	0.57
	Mean		0.361
	SD		0.118
	N		10

Individual Animal Organ-to-Brain Weigh Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female	Day(s) Relative to Start Date						
512 mg/kg/day Group 2	Adrenal /BrW (Ratio)	Heart /BrW (Ratio)	Kidneys /BrW (Ratio)	Liver /BrW (Ratio)	Ovaries with oviducts/BrW (Ratio)	Spleen /BrW (Ratio)	Thymus /BrW (Ratio)
	7031	0.036	0.44	0.93	3.90	0.058	0.30
7032	0.036	0.39	0.93	3.62	0.058	0.21	0.218
7033	0.042	0.39	0.97	3.75	0.070	0.27	0.265
7034	0.032	0.39	0.84	3.30	0.059	0.20	0.256
7035	0.035	0.44	0.84	3.97	0.074	0.22	0.214
7036	0.034	0.44	0.95	4.75	0.069	0.32	0.258
7037	0.031	0.40	0.84	3.15	0.051	0.21	0.197
7038	0.044	0.46	0.97	3.75	0.071	0.23	0.332
7039	0.032	0.40	0.93	3.99	0.057	0.28	0.183
7040	0.038	0.45	1.01	4.43	0.076	0.36	0.208
Mean	0.0361	0.420	0.920	3.862	0.0644	0.261	0.2366
SD	0.0043	0.028	0.062	0.476	0.0086	0.054	0.0434
N	10	10	10	10	10	10	10

Individual Animal Organ-to-Brain Weigh Ratios  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female	Day(s) Relative to Start Date	Uterus (BW) (Ratio)
512 mg/kg/day Group 2		
	7031	0.23
	7032	0.26
	7033	0.27
	7034	0.21
	7035	0.20
	7036	0.23
	7037	0.29
	7038	0.24
	7039	0.19
	7040	0.20
	Mean	0.232
	SD	0.033
	N	10

Individual Animal Organ-to-Brain Weigh Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female	Day(s) Relative to Start Date						
1024 mg/kg/day Group 3	Adrenal /BrW (Ratio)	Heart /BrW (Ratio)	Kidneys /BrW (Ratio)	Liver /BrW (Ratio)	Ovaries with oviducts/BrW (Ratio)	Spleen /BrW (Ratio)	Thymus /BrW (Ratio)
	7051	0.026	0.38	0.80	3.29	0.063	0.26
7052	0.035	0.43	0.93	4.30	0.056	0.25	0.299
7053	0.029	0.41	0.78	3.64	0.056	0.26	0.215
7054	0.038	0.43	0.76	3.54	0.061	0.25	0.169
7055	0.032	0.45	0.98	3.87	0.069	0.24	0.263
7056	0.031	0.38	0.86	3.43	0.051	0.29	0.301
7057	0.026	0.42	0.89	3.71	0.068	0.28	0.270
7058	0.031	0.42	0.82	3.29	0.051	0.22	0.175
7059	0.039	0.45	0.99	3.35	0.073	0.27	0.222
7060	0.037	0.39	0.86	3.50	0.056	0.17	0.233
Mean	0.0325	0.416	0.866	3.592	0.0603	0.248	0.2332
SD	0.0047	0.026	0.090	0.310	0.0079	0.035	0.0489
N	10	10	10	10	10	10	10

Individual Animal Organ-to-Brain Weight Ratios  
 PSL Study Number 43166  
 A 28-Day Dietary Study in Rats

Sex: Female	mg/kg/day	Day(s) Relative to Start Date	Uterus (g/W) (Ratio)
1024	Group 3		
		7051	0.21
		7052	0.22
		7053	0.62
		7054	0.27
		7055	0.31
		7056	0.21
		7057	0.25
		7058	0.21
		7059	0.46
		7060	0.25
	Mean		0.301
	SD		0.136
	N		10

Individual Animal Organ-to-Brain Weigh Ratios

PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female		Day(s) Relative to Start Date					
1536 mg/kg/day Group 4	Adrenal /BrW (Ratio)	Heart /BrW (Ratio)	Kidneys /BrW (Ratio)	Liver /BrW (Ratio)	Ovaries with oviducts/BrW (Ratio)	Spleen /BrW (Ratio)	Thymus /BrW (Ratio)
	7071	0.032	0.40	0.87	4.03	0.071	0.30
7072	0.037	0.42	0.93	3.80	0.070	0.27	0.227
7073	0.038	0.47	0.89	4.00	0.072	0.26	0.195
7074	0.031	0.38	0.91	3.44	0.050	0.19	0.182
7075	0.038	0.40	0.88	4.31	0.071	0.23	0.215
7076	0.040	0.41	1.00	4.12	0.072	0.26	0.329
7077	0.031	0.43	0.91	3.78	0.061	0.26	0.300
7078	0.042	0.43	0.93	3.67	0.067	0.25	0.303
7079	0.045	0.49	0.83	3.62	0.078	0.28	0.216
7080	0.032	0.39	0.83	3.65	0.062	0.23	0.299
Mean	0.0365	0.420	0.898	3.842	0.0676	0.254	0.2583
SD	0.0050	0.036	0.049	0.267	0.0078	0.031	0.0561
N	10	10	10	10	10	10	10

Individual Animal Organ-to-Brain Weigh Ratios  
PSL Study Number 43166  
A 28-Day Dietary Study in Rats

Sex: Female	Day(s) Relative to Start Date	Uterus /BW (Ratio)
1536 mg/kg/day Group 4		
	7071	0.23
	7072	0.26
	7073	0.27
	7074	0.25
	7075	0.24
	7076	0.24
	7077	0.19
	7078	0.21
	7079	0.27
	7080	0.26
	Mean	0.242
	SD	0.028
	N	10



## **APPENDIX T: HISTOPATHOLOGY**

### **PRODUCT IDENTIFICATION**

Soy Leghemoglobin Preparation

#### **Submitted By:**

HSRL  
Histo-Scientific Research Laboratories  
5930 Main Street  
Mount Jackson, VA 22842



**PATHOLOGY REPORT**

**SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS**

**Product Safety Labs (PSL) Study Number 43166**

**Prepared by**

**HSRL**  
Histo-Scientific Research Laboratories  
5930 Main Street  
Mount Jackson, VA 22842

**Testing Facility**

Product Safety Labs  
2394 US Highway 130  
Dayton, NJ 08810

**Sponsor**

Impossible Foods, Inc.  
525 Chesapeake Dr.  
Redwood City, CA 94063

July 24, 2017

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**1.0 GLP Compliance Statement- Histopathology Slide Preparation**

The histological slide preparation portion of Product Safety Labs Study Number 43166, which was performed at Histo-Scientific Research Laboratories (HSRL), 5930 Main Street, Mount Jackson, VA 22842, was conducted in compliance with U.S. FDA GLP: 21 CFR Part 58, 1987.

(b) (6)

Craig Zook  
Principal Investigator  
Histo-Scientific Research Laboratories (HSRL)


Date 7/24/17

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Impossible Foods, Inc.  
PSL Study Number 43166

**2.0 GLP Compliance Statement- Histopathology Evaluation**

The histological slide evaluation portion of Product Safety Labs Study Number 43166, which was performed at Histo-Scientific Research Laboratories (HSRL), 5930 Main Street, Mount Jackson, VA 22842, was conducted in compliance with U.S. FDA GLP: 21 CFR Part 58, 1987.

(b) (6)

  
Daniel G. Branstetter, DVM, PhD, DACVP  
Principal Investigator  
Histo-Scientific Research Laboratories (HSRL)

7/24/17

Date

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PSL Study Number 43166

### 3.0 Executive Summary

The objective of this study was to evaluate the potential subchronic toxicity of Soy Leghemoglobin Preparation in male and female rats continuously exposed to the test substance in the diet for at least 28 days. A no-observed-adverse-effect-level (NOAEL) was sought for each sex.

**Methods:** According to the protocol, 80 rats (40 male and 40 female) were assigned to four treatment groups. Following the in-life procedures, animals were euthanized and subjected to a gross necropsy. Protocol-specified tissues were collected and forwarded to HSRL for histological processing to microscope slides. The resulting microscopic slides were evaluated by Daniel G. Branstetter, DVM, PhD, DACVP of HSRL. This pathology report by HSRL presents the results of the gross and microscopic evaluation of protocol-required tissues from all animals in Groups 1 and 4 and gross lesions from all animals in all groups. In addition, based on target organs identified during slide evaluation, the ovaries, uterus, vagina, cervix and oviducts for all females in Groups 2 and 3 were processed, embedded in paraffin, sectioned, stained with hematoxylin and eosin (H&E) and evaluated microscopically.

**Conclusion:** The objective of this study was to evaluate the potential subchronic toxicity of Soy Leghemoglobin Preparation in male and female rats continuously exposed to the test substance in the diet for at least 28 days. A no-observed-adverse-effect-level (NOAEL) was sought for each sex.

There were no early deaths in this study. There were no treatment-related effects in males or females. The NOAEL for male and female rats was established at the maximum dose tested, 1536 mg/kg/day.

#### 4.0 Introduction

##### 4.1 Protocol

This report presents the histopathology results of a 28 day study of Soy Leghemoglobin Preparation when administered in the diet to rats, PSL Study Number 43166, Impossible Foods, Inc., Redwood City, CA. All in-life procedures and tissue harvests were performed at Product Safety Labs under the direction of Mithila Shitut, Study Director. Histology was performed at HSRL and microscopic evaluation was completed by Daniel G. Branstetter, DVM, PhD, DACVP at HSRL.

##### 4.2 Objective

The objective of this study was to evaluate the potential subchronic toxicity of Soy Leghemoglobin Preparation in male and female rats continuously exposed to the test substance in the diet for at least 28 days. A no-observed-adverse-effect-level (NOAEL) was sought for each sex.

#### 5.0 Methods

##### 5.1 Compliance Statement

The histology and pathology portions of this study performed by HSRL were conducted in compliance with U.S. FDA GLP: 21 CFR Part 58, 1987.

##### 5.2 Study Design

According to the protocol, 80 animals (40 males and 40 females) were enrolled in this study. The study design is further described in Table 1 as follows:

**Table 1. Dose Levels**

Group	Number Animals/Group Male/Female	Dietary Dose Level/ Target Exposure of Active Ingredient (mg/kg/day)	Dietary Dose Level/Target Exposure of Test Substance <sup>a</sup> (mg/kg/day)
1	10/10	0	0
2	10/10	250	512
3	10/10	500	1024
4	10/10	750	1536

<sup>a</sup> Based on 48.82% active ingredient (AI, Soy Leghemoglobin) of Soy Leghemoglobin Preparation lot # PP-PGM2-16-088-301

##### 5.3 Necropsy

At terminal sacrifice on Day 29 for males and Day 30 for females, all animals were euthanized and subjected to a gross necropsy. Necropsies included examination of the external surface of the body, all orifices, musculoskeletal system, and the cranial, thoracic, abdominal, and pelvic cavities, with their associated organs and tissues. At scheduled termination, the following organs were weighed: adrenals (combined), brain, epididymides (combined), heart, kidneys (combined), liver, ovaries with oviducts (combined), spleen, testes (combined), thymus, and uterus. The following organs and tissues from all animals were preserved in 10% neutral buffered formalin:

accessory genital organs (prostate and seminal vesicles)	all gross lesions
adrenals	aorta
	bone (femur)

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PSL Study Number 43166

bone marrow (from femur and sternum)	oviducts
brain – 3 sections including medulla/pons, cerebellar, and cerebral cortex	pancreas
cecum	parathyroid
cervix	peripheral nerve (sciatic)
colon	pharynx
duodenum	pituitary gland
esophagus	rectum
Harderian gland	salivary glands (sublingual, submandibular, and parotid)
heart	skeletal muscle
ileum with Peyer's patches	skin
jejunum	spinal cord - 3 levels: cervical, mid-thoracic, and lumbar
kidneys	spleen
larynx	sternum
liver	stomach
lungs	thymus
lymph node mandibular	thyroid
lymph node mesenteric	trachea
mammary gland	urinary bladder
nasal turbinates	uterus
nose	vagina
ovaries	

The epididymides, eyes, optic nerve and testes from all animals were preserved in modified Davidson's fixative and then stored in ethanol.

#### 5.4 Histological Processing

Protocol-required tissues were forwarded to HSRL where the preserved organs and tissues from all animals in the control and high dose groups (Groups 1 and 4, respectively) and gross lesions from all animals in all groups were processed, embedded in paraffin, sectioned and stained with hematoxylin and eosin (H&E). In addition, based on target organs identified during slide evaluation, the ovaries, uterus, vagina, cervix and oviducts for all females in Groups 2 and 3 were processed, embedded in paraffin, sectioned, and stained with hematoxylin and eosin (H&E). Animal information from PSL's Gross Pathology Results was entered into Pristima<sup>®</sup> at HSRL. All microscopic slides were evaluated and microscopic findings were entered directly into Pristima<sup>®</sup> by Daniel G. Branstetter, DVM, PhD, DACVP of HSRL. Gross to microscopic correlations and the incidence of microscopic findings are presented in the Histopathology Incidence Tables portion of this report.

A pathology peer review of reproductive organs from all female animals was performed by Karen S. Regan, DVM, DABT, DACVP. This pathology report reflects the consensus opinion of the Study Pathologist, Dr. Daniel Branstetter, and the Peer Review Pathologist, Dr. Karen Regan. As per Protocol Amendment No. 3, a Peer Review Statement is included in the final study report.

Within the Histopathology Incidence Tables, the following abbreviations apply:

M=Male  
F=Female  
1>=Minimal or Present  
2>=Mild  
3>=Moderate  
4>=Marked  
5>=Severe



## 6.0 Results

### 6.1 Animal Mortality

There were no early deaths among the animals submitted for histopathological evaluation.

### 6.2 Macroscopic Observations

At the Day 29/30 time point, there were no macroscopic findings related to the administration of the test substance, Soy Leghemoglobin Preparation, in male or female rats. In the female rats, the presence of "fluid filled" uteri (which correlated with dilation), typically associated with normal proestrus/estrus stage of the estrous cycle, was decreased in rats treated with 512 and 1536 mg/kg/day Soy Leghemoglobin Preparation. Fluid filled uteri were noted in 4 out of 10 females at 0 mg/kg/day (Group 1 Animals 7013, 7017, 7018, and 7020), in 0 out of 10 females at 512 mg/kg/day, in 1 out of 10 females at 1024 mg/kg/day (Group 3 Animal 7053), and in 0 out of 10 females at 1536 mg/kg/day. Fluid filled uteri correlated with the estrus stage of the estrous cycle, and higher individual uterine weights, and is a normal finding with this stage of the cycle. The decreased macroscopic incidence of fluid filled uteri in treated female rats correlated with lower incidences of estrus, resulting in significantly decreased uterine weights in the 512 and 1536 mg/kg/day groups. Notably, the incidences of animals in metestrus in the treated groups was not dose-related.

The remaining macroscopic observations at the Day 29/30 time point were also of sporadic incidence and showed no trends/patterns to suggest a relationship to administration of Soy Leghemoglobin Preparation. These findings included testis and epididymis small and/or soft right which had a microscopic correlate of atrophy and aspermia, respectively, in control group Animal 7002; brain depressed area, which was an artifact confirmed microscopically, in Group 3 Animal 7047; and spleen stricture, with no microscopic correlate, in Group 3 Animal 7055.

### 6.3 Microscopic Observations

At the Day 29/30 time point, there were no Soy Leghemoglobin Preparation-related effects.

There was a decrease in the incidence of dilated uterine lumens in the 512 and 1536 mg/kg/day rats compared to controls. The uteri were dilated in 4 out of 10 females at 0 mg/kg/day (Animals 7013, 7017, 7018, and 7020), which was consistent with estrus. There were no females with dilated uterine lumens in the 512 and 1536 mg/kg/day groups and two out of 10 in the 1024 mg/kg/day group (Animals 7053 and 7059), which correlated with lower incidences of animals in the proestrus/estrus stages of the estrous cycle. Microscopically, 512 and 1536 mg/kg/day rats tended to be in the metestrus stage of the estrous cycle which correlated with the lower weights and was an unusual distribution. However, the presence of both new and old corpora lutea in females from all groups indicates that these females were cycling normally and there were no treatment-related effects on the estrous cycle.

All other microscopic findings at the Day 29/30 time point were also unrelated to administration of Soy Leghemoglobin Preparation and can be observed in the age and strain of rats used in this study (Sugimoto *et al*, 2000; Percy and Barthold, 2007; McInnes, 2012).

## 7.0 Conclusion

The objective of this study was to evaluate the potential subchronic toxicity of Soy Leghemoglobin Preparation in male and female rats continuously exposed to the test substance in the diet for at least 28 days. A no-observed-adverse-effect-level (NOAEL) was sought for each sex.

There were no early deaths in this study. There were no treatment-related effects in males or females. The NOAEL for male and female rats was established at the maximum dose tested, 1536 mg/kg/day.

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Impossible Foods, Inc.  
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Signature:

(b) (6)

Daniel G. Branstetter, DVM, PhD, DACVP  
Study Pathologist

7/24/17  
Date

#### REFERENCES

McInnes EF. *Background Lesions in Laboratory Animals, A Color Atlas*. Edinburgh: Saunders Elsevier, 2012.

Percy D and S Barthold. *Pathology of Laboratory Rodents and Rabbits*. 3rd ed. Ames, Iowa: Blackwell Publishing Professional; 2007.

Sugimoto K, Shibuya K, Ihara M, Saitoh T, Itabashi M, and T Nunoya. Background Data on Organ Weights and Histopathological Lesions in Crj:CD(SD)IGS Rats for 4-, 13- and 26-week Repeated-Dose Toxicity Studies. *Biological Reference Data on CD(SD)IGS Rats-2000*. Tokyo: BEST PRINTING Co. Ltd.; pp 79-87, 2000.

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**Appendix A. Histopathology Incidence Tables (Expanded Summary Report of  
Histopathology Day 29/30 Animals)**

Expanded Summary Report of Histopathology

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Printed: 03/24/2017 08:49:21 AM  
Platform: Version 6.4.0 Build No. HSR151

HSRL

Study: U106

Study Title: SOY LECHEMOKULCHIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Lechemokulchin Preparation

Rat Sprague-Dawley

28 Day Dietary

	Males			
	Dosage Group	Control	1	2
	Number of Animals:	10	1	10
	Number Examined:	10	4	10
	Number Unrecoverable:	0	0	0
<b>Adrenal glands</b>	Number examined:	10	0	10
	Number unrecoverable:	0	0	0
<b>Vascular, zona fasciculata</b>	1+	1	0	0
	Total Finding Incidence:	1	0	0
<b>Aorta</b>	Number examined:	10	0	10
	Number unrecoverable:	10	0	10
<b>Bone marrow, Femur</b>	Number examined:	10	0	10
	Number unrecoverable:	10	0	0
<b>Hyposcellularity</b>	1+	0	0	1
	Total Finding Incidence:	0	0	1
<b>Bone Marrow, Sternum</b>	Number examined:	10	0	10
	Number unrecoverable:	10	0	10

Expanded Summary Report of Histopathology

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Protocol #: Vantage 6-40 Bldg 06, HSRL51

HSRL

Study: 13166

Study Title: SOY LEGBHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Leptemoglobin Preparation

Rat System: Dowley

78 Day Dietary

	Male	Dosage Group		
		Control	3	1
		Number of Animals:	10	10
		Number Examined:	10	10
		Number Unrecoverable:	0	0
Brain		Number examined:	10	10
		Number unrecoverable:	0	0
Amiot		1:	0	0
		Total Feeding Incidences:	0	0
Cecum		Number examined:	10	10
		Number unrecoverable:	0	0
Colon		Number examined:	10	10
		Number unrecoverable:	0	0
Duodenum		Number examined:	10	10
		Number unrecoverable:	0	0

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Platform: Version 6.40 Build 06.HSR151

HSRL

Study: 1316

Study Title: SOY LEGLHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Leghemoglobin Preparation

Rat Sprague-Dawley

28 Day Dietary

	Males		
	Dosage Group:	Cont'd	1
	Number of Animals:	10	10
	Number Examined:	10	10
	Number Unrecoverable:	0	0
<b>Epididymides</b>	Number examined:	10	10
	Number unrecoverable:	0	0
<b>Asperms</b>	1:	0	0
	Total Finding Incidence:	0	0
<b>Uterus, cellular, normal</b>	1:	0	2
	Total Finding Incidence:	0	2
<b>Granulosa, sperm</b>	1:	0	0
	Total Finding Incidence:	0	0
<b>Euplasms</b>	Number examined:	10	10
	Number unrecoverable:	0	0
<b>Eyes</b>	Number examined:	10	10
	Number unrecoverable:	0	0
<b>Rosettes, zellio</b>	1:	0	2
	Total Finding Incidence:	0	2
<b>Four</b>	Number examined:	10	10
	Number unrecoverable:	0	0

Expanded Summary Report of Histopathology

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Platform: Version 6.40 Build 86.HSR1.01

HSRL

Study: U100

Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Leghemoglobin Preparation

Rat Species-Diary

28 Day-Dietary

	Males		
	Dosage Group	Control	1
	Number of Animals:	10	10
	Number Examined:	10	10
	Number Unavailable:	0	0
<b>Femur</b>	Number examined:	10	10
	Number unavailable:	0	0
<b>Harderian gland</b>	Number examined:	10	10
	Number unavailable:	0	0
<b>Thyroid gland</b>	1:	0	0
	Total Finding Incidence:	0	0
<b>Heart</b>	Number examined:	10	10
	Number unavailable:	0	0
<b>Degeneration, myofiber</b>	1:	0	0
	Total Finding Incidence:	0	0
<b>Infiltration, mixed cell</b>	1:	0	1
	Total Finding Incidence:	0	1
<b>Infiltration, mononuclear cell</b>	1:	0	0
	Total Finding Incidence:	0	0
<b>Ileum</b>	Number examined:	10	10
	Number unavailable:	0	0

Expanded Summary Report of Histopathology

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Platform: Version 6.40 Build 66.HSR.L01

HSRL

Study: 0316

Study Title: SOY LEGLHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Leghemoglobin Preparation

Rat Sprague-Dawley

28 Day Dietary

	Males			
	Dosage Group	Control	3	1
	Number of Animals:	10	1	10
	Number Examined:	10	1	10
	Number Unretrievable:	0	0	0
Heart	Number examined:	10	0	10
	Number unretrievable:	10	0	10
Lung	Number examined:	10	0	10
	Number unretrievable:	10	0	10
Kidney	Number examined:	10	0	10
	Number unretrievable:	0	0	0
Basophilic nodules	1:	2	0	1
Total Finding Incidence	2	0	1	
Exacerbation, tubular epithelial cells	1:	1	0	0
Total Finding Incidence	1	0	0	
Inflammation, mononuclear cells, interstitial	1:	1	0	1
Total Finding Incidence	1	0	1	
Larynx	Number examined:	10	0	10
	Number unretrievable:	0	0	0



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Platform: Version 6.4.0 Build 06.HSRLE01

HSRL

Study: 13106

Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
Test Article: Soy Leghemoglobin Preparation

Rat Sprague-Dawley

28 Day Dietary

	Males			
	Dosage Group	Control	3	1
	Number of Animals:	10	1	10
	Number Examined:	10	1	10
	Number Unavailable:	0	0	0
Larynx	Number examined:	10	0	10
	Number unavailable:	8	0	8
	1+:	0	0	1
	Total Finding Incidence:	0	0	1
Inflammation, neutrophil	1+:	2	0	1
	Total Finding Incidence:	2	0	1
Liver	Number examined:	10	0	10
	Number unavailable:	2	0	1
	1+:	8	0	9
	Total Finding Incidence:	8	0	9
Necrosis	1+:	1	0	0
	Total Finding Incidence:	1	0	0
Metastasis, hepatocellular, NOS	1+:	1	0	2
	Total Finding Incidence:	1	0	2
Lungs	Number examined:	10	0	10
	Number unavailable:	10	0	10
Lymph Node, Mandibular	Number examined:	10	0	10
	Number unavailable:	10	0	10

Expanded Summary Report of Histopathology

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Printed: 07/24/2017 08:49:21 AM

Platform: Version 6.4.0 Build 63.HSR101

HSRL

Study: 03166

Study Title: SOY LECITHOGLUCIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Lecithoglucin Preparation

Rat Sprague-Dawley

28 Day Dietary

	Male			
	Dosage Group	Control	1	1
	Number of Animals:	10	1	10
	Number Examined:	10	1	10
	Number Unrecoverable:	0	0	0
Lymph Node, Mandibular	Number examined:	10	0	10
	Number unrecoverable:	10	0	10
Lymph Node, Mesenteric	Number examined:	10	0	10
	Number unrecoverable:	10	0	10
Mammary Gland	Number examined:	10	0	10
	Number unrecoverable:	9	0	10
Atrophy	1+	1	0	0
	Total Finding Incidence:	1	0	0
Nose and Nasal Turbinates	Number examined:	10	0	10
	Number unrecoverable:	10	0	10

Expanded Summary Report of Histopathology

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Prisma3; Version 0.4.0 Build 86.HSRL01

HSRL

Study: 43166

Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Leghemoglobin Preparation

Rat: Sprague-Dawley

28 Day/Dietary

	Males			
	Dosage Group	Control	3	4
	Number of Animals	10	1	10
	Number Examined	10	1	10
	Number Unremarkable	0	0	0
Optic Nerves	Number examined	10	0	10
	Number unremarkable	10	0	10
Pancreas	Number examined	10	0	10
	Number unremarkable	10	0	10
Parathyroid Glands	Number examined	10	0	10
	Number unremarkable	10	0	10
Peripheral nerve (sciatic)	Number examined	10	0	10
	Number unremarkable	10	0	10

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Platform: Version 6.40 Build 60.HSR151

HSRL

Study: U166

Study Title: SOY LEGLHEMAGGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Leghemagglutinin Preparation

Rat Sprague-Dawley

28 Day Dietary

	Males			
	Dosage Group	Control	3	1
	Number of Animals:	10	1	10
	Number Examined:	10	1	10
	Number Unretrievable:	0	0	0
Peyer's Patches	Number examined:	10	0	10
	Number unretrievable:	10	0	10
Plazenta	Number examined:	10	0	10
	Number unretrievable:	10	0	10
Pituitary Gland	Number examined:	10	0	10
	Number unretrievable:	10	0	10
Prostate Gland	Number examined:	10	0	10
	Number unretrievable:	7	0	9
Infiltration, mononuclear cell	1+	3	0	1
	Total Finding Incidence:	3	0	1
Secretion, increased amount	1+	1	0	0
	Total Finding Incidence:	1	0	0

Expanded Summary Report of Histopathology

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HSRL

Study: 13166

Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Leghemoglobin Preparation

Int Systems: Cowley

28 Day Dietary

	Male		
	Dosage Group	Control	1
	Number of Animals:	10	10
	Number Examined:	10	10
	Number Unrecoverable:	0	0
Rectum	Number examined:	10	10
	Number unrecoverable:	0	0
Salivary gland, Parotid	Number examined:	10	10
	Number unrecoverable:	0	0
Salivary gland, Sublingual	Number examined:	10	10
	Number unrecoverable:	0	0
Infiltration, mononuclear cell	1+	1	0
Total Finding Incidence		1	0
Salivary gland, Submandibular	Number examined:	10	10
	Number unrecoverable:	0	0

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HSRL

Study: 43166

Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Test Article: Soy Leghemoglobin Preparation

Rat Sprague-Dawley

28 Day Dietary

	Males			
	Dosage Group:	Control	3	4
	Number of Animals:	10	1	10
	Number Examined:	10	1	10
	Number Unremarkable:	0	0	0
Seminal Vesicles	Number examined:	10	0	10
	Number unremarkable:	10	0	10
Skeletal Muscle	Number examined:	10	0	10
	Number unremarkable:	10	0	10
Skin	Number examined:	10	0	10
	Number unremarkable:	10	0	10
Spinal Cord, Cervical	Number examined:	10	0	10
	Number unremarkable:	10	0	10

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HSRL

Study: 43166

Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Leghemoglobin Preparation

Rat/Sprague-Dawley

28 Day/Dietary

		Males		
	Dosage Group	Control	3	4
	Number of Animals	10	1	10
	Number Examined	10	1	10
	Number Unremarkable	0	0	0
Spinal Cord, Lumbar	Number examined	10	0	10
	Number unremarkable	10	0	10
Spinal Cord, Midthoracic	Number examined	10	0	10
	Number unremarkable	10	0	10
Spleen	Number examined	10	0	10
	Number unremarkable	10	0	10
Stomach	Number examined	10	0	10
	Number unremarkable	10	0	10

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HSRL

Study: 13166

Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Leghemoglobin Preparation

Rat Sprague-Dawley

28 Days Dietary

	Males			
	Dosage Group	Control	1	3
	Number of Animals	10	1	10
	Number Examined	10	1	10
	Number Unexamined	0	0	0
Stomach	Number examined:	10	0	10
	Number unexamined:	10	0	9
Infiltration, mononuclear cell	1+	0	0	1
	Total Finding Incidence	0	0	1
Testes	Number examined:	10	0	10
	Number unexamined:	8	0	7
Atrophy, tubules	1+	1	0	1
	1+	1	0	0
	Total Finding Incidence	2	0	1
Decreased number, round spermatids	1+	0	0	1
	Total Finding Incidence	0	0	1
Vacuolation, Sertoli cells	1+	1	0	2
	Total Finding Incidence	1	0	2
Thymus	Number examined:	10	0	10
	Number unexamined:	7	0	3
Increased number, macrophages, lymphic body	1+	1	0	7
	Total Finding Incidence	3	0	7



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HSRL

Study: 43166

Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Leghemoglobin Preparation

Rat: Sprague-Dawley

28 Day: Dietary

		Males			
		Desage Group:	Control	3	4
		Number of Animals	10	1	10
		Number Examined	10	1	10
		Number Unremarkable	0	0	0
Thyroid Gland	Number examined	10	0	10	
	Number unremarkable	10	0	10	
Trachea	Number examined	10	0	10	
	Number unremarkable	10	0	10	
Urinary Bladder	Number examined	10	0	10	
	Number unremarkable	10	0	10	

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HSRL

Study: 43166

Study Title: SOY LEGHEMAGGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Leghemaglobin Preparation

HSR Synopsi-Dowley

28 Day-Dietary

	Female				
	Dosage Group: Control	2	3	4	
	Number of Animals:	10	10	10	
	Number Examined:	10	10	10	
	Number Unavailable:	0	0	0	
Adrenal glands	Number examined:	10	0	0	10
	Number unavailable:	10	0	0	10
Aorta	Number examined:	10	0	0	10
	Number unavailable:	10	0	0	10
Bone marrow, Femur	Number examined:	10	0	0	10
	Number unavailable:	10	0	0	9
Decreased myeloid erythroid ratio	F:	0	0	0	1
Total Finding Incidence	F:	0	0	0	1
Bone Marrow, Sternum	Number examined:	10	0	0	10
	Number unavailable:	10	0	0	9
Decreased myeloid erythroid ratio	F:	0	0	0	1
Total Finding Incidence	F:	0	0	0	1

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Study: 43166

Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Leghemoglobin Preparation

Rat Sprague-Dawley

28 Day Dietary

		Females				
		Desage Group	Control	2	3	-1
		Number of Animals	10	10	10	10
		Number Examined	10	10	10	10
		Number Unremarkable	0	0	0	0
Brain	Number examined	10	0	0	10	
	Number unremarkable	10	0	0	10	
Cecum	Number examined	10	0	0	10	
	Number unremarkable	10	0	0	10	
Cervix	Number examined	10	10	10	10	
	Number unremarkable	10	10	10	10	
Colon	Number examined	10	0	0	10	
	Number unremarkable	10	0	0	10	

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HSRL

Study: 43166

Study Title: SOY LIGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Lighemoglobin Preparation

Rat Sprague-Dawley

28 Day Dietary

	Females				
	Dosage Group	Count	2	3	4
	Number of Animals:	10	10	10	10
	Number Examined:	10	10	10	10
	Number Unavailable:	0	0	0	0
Coelom	Number examined:	10	0	0	10
	Number unavailable:	10	0	0	10
Esophagus	Number examined:	10	0	0	10
	Number unavailable:	10	0	0	10
Eyes	Number examined:	10	0	0	10
	Number unavailable:	0	0	0	10
Rodentia, sllw	1 >	1	0	0	0
	Fetal Finding Incidence:	1	0	0	0
Uterus	Number examined:	10	0	0	10
	Number unavailable:	10	0	0	10

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HSRL

Study: 13166

Study Title: SOY LEGHEMAGLUCIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Leghemaglobin Preparation

Raf/Sygnia-Dowley

28 Day-Dietary

	Foci/les				
	Dosage Group	Control	2	3	1
	Number of Animals:	10	10	10	10
	Number Examined:	10	10	10	10
	Number Unavailable:	0	0	0	0
<hr/>					
Harderian glands	Number examined:	10	0	0	0
	Number unavailable:	7	0	0	0
Inflammation, mononuclear cell	1+	3	0	0	0
	Total Finding Incidence	3	0	0	0
<hr/>					
Heart	Number examined:	10	0	0	0
	Number unavailable:	7	0	0	0
Inflammation, mononuclear cell	1+	3	0	0	0
	Total Finding Incidence	3	0	0	0
<hr/>					
Bladder	Number examined:	10	0	0	0
	Number unavailable:	10	0	0	0
<hr/>					
Jejunum	Number examined:	10	0	0	0
	Number unavailable:	10	0	0	0

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HSRL

Study: 13166

Study Title: SOY LEGHEMAGGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
Test Article: Soy Leghemaglobin Preparation

Rat Sprague-Dawley

28 Day Dietary

	Female	Dosage Group:			
		Control	2	3	4
		10	10	10	10
		10	10	10	10
		0	0	0	0
Kidneys	Number examined:	10	0	0	10
	Number unremarkable:	5	0	0	7
Basophilic tubules	1+	3	0	0	1
	Total Finding Incidence:	3	0	0	1
Eosinophilic tubules	1+	1	0	0	0
	Total Finding Incidence:	1	0	0	0
Infiltration, mononuclear cell, interstitial	1+	2	0	0	2
	Total Finding Incidence:	2	0	0	2
Lesion	Number examined:	10	0	0	10
	Number unremarkable:	10	0	0	9
Infiltration, neutrophil	1+	0	0	0	1
	Total Finding Incidence:	0	0	0	1
Liver	Number examined:	10	0	0	10
	Number unremarkable:	7	0	0	7
Infiltration, mixed cell	1+	3	0	0	0
	Total Finding Incidence:	3	0	0	0
Lungs	Number examined:	10	0	0	10
	Number unremarkable:	9	0	0	10

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HSRL

Study: 43166

Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Leghemoglobin Preparation

Rat Sprague-Dawley

38 Exp./Dietary

	Female	Dosage Group				
		Control	2	3	4	
		Number of Animals:	10	10	10	10
		Number Examined:	10	10	10	10
		Number Unrecoverable:	0	0	0	0
Lungs		Number examined:	10	0	0	10
		Number unrecoverable:	0	0	0	10
Inflammation, mononuclear cell		1+	1	0	0	0
		Total Finding Incidence:	1	0	0	0
Lymph Node, Mandibular		Number examined:	10	0	0	10
		Number unrecoverable:	10	0	0	10
Lymph Node, Mesenteric		Number examined:	10	0	0	10
		Number unrecoverable:	10	0	0	10
Mammary Gland		Number examined:	10	0	0	10
		Number unrecoverable:	0	0	0	10
Calcium (shells)		2+	1	0	0	0
		Total Finding Incidence:	1	0	0	0

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Study: 43166

Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
Test Article: Soy Leghemoglobin Preparation

Rat Sprague-Dawley

28 Days Dietary

	Females				
	Dosage Group	Control	2	3	1
	Number of Animals:	10	10	10	10
	Number Examined:	10	10	10	10
	Number Unremarkable:	0	0	0	0
Nose and Nasal Turbinates	Number examined:	10	0	0	10
	Number unremarkable:	10	0	0	10
Optic Nerves	Number examined:	10	0	0	10
	Number unremarkable:	10	0	0	10
Ovaries	Number examined:	10	10	10	10
	Number unremarkable:	10	10	10	9
Cyst, luteinized	>=	0	0	0	1
	Total Finding Incidence:	0	0	0	1
Oviducts	Number examined:	10	10	10	10
	Number unremarkable:	10	10	10	10



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HSRL

Study: 1106

Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Leghemoglobin Preparation

Rat Sprague-Dawley

28 Day Dietary

	Females				
	Dosage Group	Control	2	3	4
	Number of Animals:	10	10	10	10
	Number Examined:	10	10	10	10
	Number Unrecoverable:	0	0	0	0
Pancreas	Number examined:	10	0	0	10
	Number unrecoverable:	10	0	0	10
Parathyroid Glands	Number examined:	9	0	0	10
	Number unrecoverable:	9	0	0	10
Peripheral nerve (sacral)	Number examined:	10	0	0	10
	Number unrecoverable:	10	0	0	10
Peyer's Patches	Number examined:	10	0	0	10
	Number unrecoverable:	9	0	0	9
Mucosal hyperplasia	0	0	0	0	1
	1	0	0	0	1
	2	0	0	0	0
	3	0	0	0	0
	4	0	0	0	0
	5	0	0	0	0
	6	0	0	0	0
	7	0	0	0	0
	8	0	0	0	0
	9	0	0	0	0
	10	0	0	0	0
	11	0	0	0	0
	12	0	0	0	0
	13	0	0	0	0
	14	0	0	0	0
	15	0	0	0	0
	16	0	0	0	0
	17	0	0	0	0
	18	0	0	0	0
	19	0	0	0	0
	20	0	0	0	0
	21	0	0	0	0
	22	0	0	0	0
	23	0	0	0	0
	24	0	0	0	0
	25	0	0	0	0
	26	0	0	0	0
	27	0	0	0	0
	28	0	0	0	0
	29	0	0	0	0
	30	0	0	0	0
	31	0	0	0	0
	32	0	0	0	0
	33	0	0	0	0
	34	0	0	0	0
	35	0	0	0	0
	36	0	0	0	0
	37	0	0	0	0
	38	0	0	0	0
	39	0	0	0	0
	40	0	0	0	0
	41	0	0	0	0
	42	0	0	0	0
	43	0	0	0	0
	44	0	0	0	0
	45	0	0	0	0
	46	0	0	0	0
	47	0	0	0	0
	48	0	0	0	0
	49	0	0	0	0
	50	0	0	0	0
	51	0	0	0	0
	52	0	0	0	0
	53	0	0	0	0
	54	0	0	0	0
	55	0	0	0	0
	56	0	0	0	0
	57	0	0	0	0
	58	0	0	0	0
	59	0	0	0	0
	60	0	0	0	0
	61	0	0	0	0
	62	0	0	0	0
	63	0	0	0	0
	64	0	0	0	0
	65	0	0	0	0
	66	0	0	0	0
	67	0	0	0	0
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	69	0	0	0	0
	70	0	0	0	0
	71	0	0	0	0
	72	0	0	0	0
	73	0	0	0	0
	74	0	0	0	0
	75	0	0	0	0
	76	0	0	0	0
	77	0	0	0	0
	78	0	0	0	0
	79	0	0	0	0
	80	0	0	0	0
	81	0	0	0	0
	82	0	0	0	0
	83	0	0	0	0
	84	0	0	0	0
	85	0	0	0	0
	86	0	0	0	0
	87	0	0	0	0
	88	0	0	0	0
	89	0	0	0	0
	90	0	0	0	0
	91	0	0	0	0
	92	0	0	0	0
	93	0	0	0	0
	94	0	0	0	0
	95	0	0	0	0
	96	0	0	0	0
	97	0	0	0	0
	98	0	0	0	0
	99	0	0	0	0
	100	0	0	0	0

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HSRL

Study: 03166

Study Title: SOY LEPHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Lepheмоglobin Preparation

Int: Sprague-Dawley

28 Day Dietary

	Females			
	Dosage Group: Control	2	3	4
	Number of Animals:	10	10	10
	Number Examined:	10	10	10
	Number Unremarkable:	0	0	0
Peyer's Patches	Number examined:	10	9	0
	Number unremarkable:	9	9	9
Mucosalization	Total Finding Incidence:	1	0	0
Flaccids	Number examined:	10	0	0
	Number unremarkable:	10	0	0
Pituitary Gland	Number examined:	10	0	0
	Number unremarkable:	8	0	0
Cyst(s) paraventricular	Total Finding Incidence:	2	0	0
Rectum	Number examined:	10	0	0
	Number unremarkable:	10	0	0
Salivary Gland, Parotid	Number examined:	10	0	0
	Number unremarkable:	9	0	0

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HSRL

Study: 43166

Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Test Article: Soy Leghemoglobin Preparation

Rat Sprague-Dawley

28 Day Dietary

	Females				
	Dosage Group	Control	2	3	4
	Number of Animals:	10	10	10	10
	Number Examined:	10	10	10	10
	Number Unavailable:	0	0	0	0
Salivary Gland, Parotid	Number examined:	10	0	0	10
	Number unavailable:	0	0	0	0
Infiltration, mononuclear cell	U	1	0	0	0
	Total Finding Incidence:	1	0	0	0
Salivary Gland, Sublingual	Number examined:	10	0	0	10
	Number unavailable:	10	0	0	10
Salivary gland, Submandibular	Number examined:	10	0	0	10
	Number unavailable:	10	0	0	10
Skeletal Muscle	Number examined:	10	0	0	10
	Number unavailable:	10	0	0	10

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HSRL

Study: 43166

Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Test Article: Soy Leghemoglobin Preparation

Rat-Sprague-Dawley

28 Day/Dietary

	Females				
	Dosage Group	Control	2	3	4
	Number of Animals:	10	10	10	10
	Number Examined:	10	10	10	10
	Number Unremarkable:	0	0	0	0
Skin	Number examined:	10	0	0	10
	Number unremarkable:	10	0	0	10
Spinal Cord, Cervical	Number examined:	10	0	0	10
	Number unremarkable:	10	0	0	10
Spinal Cord, Lumbar	Number examined:	10	0	0	10
	Number unremarkable:	10	0	0	10
Spinal Cord, Midthoracic	Number examined:	10	0	0	10
	Number unremarkable:	10	0	0	10

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HSRL

Study: 13106

Study Title: SOY LEGHEMAGGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Leghemaglobin Preparation

Cell System/Device

28 Day Dietary

	Females				
	Dosage Group	Control	2	3	4
	Number of Animals:	10	10	10	10
	Number Examined:	10	10	10	10
	Number Unrecoverable:	0	0	0	0
Spleen	Number examined:	10	0	1	10
	Number unrecoverable:	0	0	1	0
Stemum	Number examined:	10	0	0	10
	Number unrecoverable:	10	0	0	10
Stomach	Number examined:	10	0	0	10
	Number unrecoverable:	10	0	0	10
Thymus	Number examined:	10	0	0	10
	Number unrecoverable:	0	0	0	1
Increased number, macrophages, angible testy	1*	1	0	0	0
	Total Finding Incidence:	1	0	0	0

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HSRL

Study: U166

Study Title: SOY LECHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
Test Article: Soy Lipohectoglobin Preparation

Rat Sprague-Dawley

28 Day Dietary

	Females				
	Dosage Group	Control	2	3	4
	Number of Animals:	10	10	10	10
	Number Examined:	10	10	10	10
	Number Unavailable:	0	0	0	0
Thyroid Gland	Number examined:	10	9	9	10
	Number unavailable:	10	0	0	10
Trachea	Number examined:	10	0	0	10
	Number unavailable:	10	0	0	10
Urinary Bladder	Number examined:	10	0	0	10
	Number unavailable:	10	0	0	10
Vacuolation, epithelium	2+	0	0	0	1
	Total Finding Incidence	0	0	0	1
Uterus	Number examined:	10	10	10	10
	Number unavailable:	0	10	8	10
Citation	2+	1	0	1	0
	3+	1	0	1	0
	Total Finding Incidence	1	0	2	0

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HSRL

Study: U10n

Study Title: SOY LEAGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Test Article: Soy Leaghemoglobin Preparation

Test Specimen Category

28 Day Dietary

	Females				
	Dosage Group	Control	2	3	4
	Number of Animals:	10	10	10	10
	Number Examined:	10	10	10	10
	Number Unrecoverable:	0	0	0	0
Vagina	Number examined:	10	10	10	10
	Number unrecoverable:	0	0	0	0
Diestrus	1-:	0	1	3	0
	Total Finding Incidence:	0	1	3	0
Estrus	1-:	1	1	2	0
	Total Finding Incidence:	1	1	2	0
Metestrus	1-:	1	8	3	9
	Total Finding Incidence:	1	8	3	9
Proestrus	1-:	2	0	2	2
	Total Finding Incidence:	2	0	2	2

Final Pathology Report  
Impossible Foods, Inc.  
PSL Study Number 43166

**Appendix A. Histopathology Incidence Tables (Individual Data Listing of Gross to  
Microscopic Correlation)**



Gross Observations			Status	Microscopic Observations
Animal #	Sex	Group		
7002	M	I		
		Epididymides, Small, right, 3 x 0.5 cm	Correlated	Epididymides, Asperma, marked, unilateral
		Testes, Small, right, 1 x 1.5 cm	Correlated	Testes, Atrophy, tubules, marked, diffuse, unilateral
		Testes, Soft, right	Correlated	Testes, Atrophy, tubules, marked, diffuse, unilateral
7017	M	3		
		Brain, Depressed Area, fecal, on left hemisphere/possible protection damage	Correlated	Brain, Artifact, present
7013	F	I		
		Uterus, Fluid filled, Noted	Correlated	Vagina, Estrus, present Uterus, Dilated, mild
7017	F	I		
		Uterus, Fluid filled, Noted	Correlated	Vagina, Estrus, present Uterus, Dilated, mild
7018	F	I		
		Uterus, Fluid filled, Noted	Correlated	Vagina, Estrus, present Uterus, Dilated, mild
7020	F	I		
		Uterus, Fluid filled, Noted	Correlated	Vagina, Estrus, present Uterus, Dilated, moderate

Gross Observations			Status	Microscopic Observations
Animal #	Sex	Group		
7053	F	3		
		Uterus, Fluid filled, Noted	Correlated	Uterus, Dilaton, moderate Vagina, Estrus, present
7055	F	3		
		Spleen, Stricture, Noted	Not Correlated	

Final Pathology Report  
Impossible Foods, Inc.  
PSL Study Number 43166

**Appendix A. Histopathology Incidence Tables (Individual Gross and Microscopic Observations)**

**Individual Gross and Microscopic Observations**

Printed: 07/24/2017 08:52:57 AM  
Pristima® Version 6.40 Build 86.HSR.L01

HSRL Study: 43166  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Test Article: Soy Leghemoglobin Preparation  
 28 Day/Dietary

Rat: Sprague-Dawley  
 Animal #: 7001  
 Group: I  
 Sex: M  
 Day Of Death: Design Phase, Day 29  
 Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal
Parathyroid Glands	No Gross Observations		One of the pair is Missing Within Normal Limits
Prostate Gland	No Gross Observations		Infiltration, mononuclear cell, minimal, multifocal

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Colon	Duodenum	Epididymides	Esophagus
Eyes	Femur	Harderian glands	Heart	Heum
Jejunum	Kidneys	Larynx	Lungs	Lymph Node, Mandibular
Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Pancreas
Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	Pituitary Gland
Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	Seminal Vesicles
Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic
Spleen	Sternum	Stomach	Testes	Thymus

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:52:57 AM  
Study: 43166 Prisma7: Version 6.4.0 Build R6.HSRL01  
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
Rat: Sprague-Dawley 28 Day/Dietary  
Animal #: 7001 Test Article: Soy Leghemoglobin Preparation  
Group: 1 Day Of Death: Dosing Phase, Day 29  
Sex: M Death Status: Terminal sacrifice

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Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
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The following tissues are within normal limits both grossly and microscopically:  
Thyroid Gland      Trachea      Urinary Bladder

Continued from previous page ...

Individual Gross and Microscopic Observations				Printed: 07/24/2017 08:52:57 AM
HSRL		Study: 43166	PrismaX Version 6.4.0 Build 86.HSRL01	
Rat: Sprague-Dawley		Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS		
Animal #: 7002		Test Article: Soy Leghemoglobin Preparation		28 Day/Dietary
Group: 1		Day Of Death:	Dosing Phase, Day 29	
Sex: M		Death Status: Terminal sacrifice		
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
Adrenal glands	No Gross Observations		Vacuolation, zona fasciculata, minimal, diffuse	
Epididymides	Small, right, 3 x 0.5 cm	Correlated	Aspermia, masked, unilateral	
Kidneys	No Gross Observations		Degeneration, tubular epithelial cell, minimal, focal	
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal Vacuolation, hepatocellular, NOS, minimal, diffuse	
Parathyroid Glands	No Gross Observations		One of the pair is Missing Within Normal Limits	
Testes	Small, right, 1 x 1.5 cm Soft, right	Correlated Correlated	Atrophy, tubules, marked, diffuse, unilateral Atrophy, tubules, marked, diffuse, unilateral	
The following protocol-specified required tissues were not examined microscopically: There are no such tissues				
The following tissues are within normal limits both grossly and microscopically:				
Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain	Cecum
Colon	Duodenum	Esophagus	Eyes	Femur
Harderian glands	Heart	Ileum	Jejunum	Larynx
Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates
Optic Nerves	Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches

Individual Gross and Microscopic Observations				
HSRL		Study: 43166	Printed: 07/24/2017 08:52:57 AM	
		Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS	PrismVer: Version 6.4.0 Build 86 HSRL01	
Rat Sprague-Dawley		Test Article: Soy Leghemoglobin Preparation	28 Day/Dietary	
Animal #: 7002	Group: 1	Sex: M	Day Of Death: Dosing Phase, Day 29	Death Status: Terminal sacrifice
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
The following tissues are within normal limits both grossly and microscopically.			Continued from previous page ...	
Pharynx	Parotid Gland	Prostate Gland	Rectum	Salivary Gland, Parotid
Salivary Gland, Sublingual	Salivary gland, Submandibular	Seminal Vesicles	Skeletal Muscle	Skin
Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic	Spleen	Stomach
Stomach	Thymus	Thyroid Gland	Trachea	Urinary Bladder

**Individual Gross and Microscopic Observations**

Printed: 07/24/2017 08:52:57 AM  
Pristima® Version 6.10 Build 86.HSR1.01

HSRL Study: 43166  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat: Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
 Animal #: 7003 Group: 1 Day Of Death: Dosing Phase, Day 29  
 Sex: M Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Heart	No Gross Observations		Degeneration, myofiber, minimal, focal
Larynx	No Gross Observations		Infiltration, neutrophil, minimal, multifocal
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal
Parathyroid Glands	No Gross Observations		Tissue Comment: Two parathyroids available for evaluation.
Salivary Gland, Parotid	No Gross Observations		Within Normal Limits One of the pair is Missing

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Colon	Duodenum	Epididymides	Esophagus
Eyes	Femur	Hartlerian glands	Heart	Jejunum
Kidneys	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric	Mammary Gland
Nose and Nasal Turbinates	Optic Nerves	Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)
Peyer's Patches	Pharynx	Pituitary Gland	Prostate Gland	Rectum



Individual Gross and Microscopic Observations				Printed: 07/24/2017 09:52:57 AM
HSRL	Study: 43166	Prisma® Version 6.4.0 Build 86.HSRL.01		
Rat Sprague-Dawley	Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS	28 Day/Dietary		
Animal #: 7003	Test Article: Soy Leghemoglobin Preparation	Group: 1	Day Of Death: Dosing Phase, Day 29	
	Sex: M	Death Status: Terminal sacrifice		
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	Seminal Vesicles	Continued from previous page ... Skeletal Muscle
Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic	Spleen
Serum	Stomach	Testes	Thymus	Thyroid Gland
Trachea	Urinary Bladder			

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:52:57 AM  
 Study: 43166 Pristima 8, Version 6.10 Build 86.HSRL01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
 Rat/Sprague-Dawley Day Of Death: Dosing Phase, Day 29  
 Animal #: 7004 Group: 1  
Sex: M Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Heart	No Gross Observations		Degeneration, myofiber, minimal, focal
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal
Parathyroid Glands	No Gross Observations		One of the pair is Missing Within Normal Limits
Thymus	No Gross Observations		Increased number, macrophages, tingible body, minimal, diffuse

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Colon	Duodenum	Epididymides	Esophagus
Eyes	Femur	Harderian glands	Beum	Jejunum
Kidneys	Larynx	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric
Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Pancreas	Parathyroid Glands
Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	Pituitary Gland	Prostate Gland
Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	Seminal Vesicles

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:52:57 AM  
 Study: 43166 Prism3: Version 6.4.0 Build 86 HSR101  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat: Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day: Dietary  
 Animal #: 7001 Group: 1 Day Of Death: Dosing Phase, Day 29  
 Sex: M Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
Continued from previous page ...				
The following tissues are within normal limits both grossly and microscopically.				
Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic
Spleen	Semen	Stomach	Testes	Thyroid Gland
Trachea	Urinary Bladder			

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:52:57 AM  
 Study: 43166 Prisma® Version 6.10 Build 86.HSRL01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation  
 Animal #: 7005 Group: I Day Of Death: Dosing Phase, Day 29  
28 Day/Dietary  
 Sex: M Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Larynx	No Gross Observations		Infiltration, neutrophil, minimal, focal
Parathyroid Glands	No Gross Observations		One of the pair is Missing Within Normal Limits
Salivary Gland, Sublingual	No Gross Observations		Infiltration, mononuclear cell, minimal, multifocal
Thymus	No Gross Observations		Increased number, macrophages, tingible body, minimal, multifocal

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Colon	Duodenum	Epididymides	Esophagus
Eyes	Femur	Harderian glands	Heart	Ileum
Jejunum	Kidneys	Liver	Lungs	Lymph Node, Mandibular
Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Pancreas
Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	Pituitary Gland
Prostate Gland	Rectum	Salivary Gland, Parotid	Salivary gland, Submandibular	Seminal Vesicles

Individual Gross and Microscopic Observations				Printed: 07/24/2017 08:52:57 AM
HSRL	Study: 43166	PrismasX Version 6.40 Build 86.HSRL01		
Rat: Sprague-Dawley	Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS	Test Article: Soy Leghemoglobin Preparation		28 Day: Dietary
Animal #: 7005	Group: 1	Day Of Death: Dosing Phase, Day 29		
	Sex: M	Death Status: Terminal sacrifice		
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
Continued from previous page ...				
The following tissues are within normal limits both grossly and microscopically:				
Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic
Spleen	Sternum	Stomach	Testes	Thyroid Gland
Trachea	Urinary Bladder			

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:52:57 AM  
 Study: 43166 Prisma3: Version 6.40 Build 86:HSRL01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat/Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
 Animal #: 7006 Group: J Day Of Death: Dosing Phase, Day 29  
 Sex: M Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Epididymides	No Gross Observations		Dobns, cellular, luminal, minimal, diffuse, bilateral
Kidneys	No Gross Observations		Basophilic, tubules, minimal, multifocal
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal Necrosis, minimal, focal
Prostate Gland	No Gross Observations		Infiltration, mononuclear cell, minimal, multifocal
Testes	No Gross Observations		Atrophy, tubules, minimal, multifocal, bilateral Vacuolation, Sertoli cells, minimal, multifocal

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Colon	Duodenum	Esophagus	Eyes
Femur	Harderian glands	Heart	Heum	Jejunum
Larynx	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric	Mammary Gland
Nose and Nasal Turbinates	Optic Nerves	Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)
Peyer's Patches	Pharynx	Pituitary Gland	Rectum	Salivary Gland, Parotid
Salivary Gland, Sublingual	Salivary gland, Submandibular	Seminal Vesicles	Skeletal Muscle	Skin

Individual Gross and Microscopic Observations				
HSRL	Study: 43166			Printed: 07/24/2017 08:52:57 AM
	Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS			Pristima® Version 6.4.0 Build 86,HSRL01
Rat Sprague-Dawley	Test Article: Soy Leghemoglobin Preparation			28 Day: Dietary
Animal #: 7006	Group: 1	Day Of Death:	Dosing Phase:	Day 29
	Sex: M	Death Status: Terminal sacrifice		
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
The following tissues are within normal limits both grossly and microscopically.				
Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic	Spleen	Stomach
Stomach	Thymus	Thyroid Gland	Trachea	Urinary Bladder

Continued from previous page ...

**Individual Gross and Microscopic Observations** Printed: 07/24/2017 08:52:57 AM

Study: 43166 Prismu# Version 6.1.0 Build 86-HSRL01

HSRL Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary

Animal #: 7007 Group: 1 Day Of Death: Death Phase, Day 29

Sex: M Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Heart	No Gross Observations		Infiltration, mononuclear cell, minimal, focal
Kidneys	No Gross Observations		Basophilia, tubules, minimal, focal
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal
Parathyroid Glands	No Gross Observations		Tissue Comment: Two parathyroids available for evaluation

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Colon	Duodenum	Epididymides	Esophagus
Eyes	Femur	Harderian glands	Ileum	Jejunum
Larynx	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric	Mammary Gland
Nose and Nasal Turbinates	Optic Nerves	Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)
Peyer's Patches	Pharynx	Pituitary Gland	Prostate Gland	Rectum
Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	Seminal Vesicles	Skeletal Muscle
Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic	Spleen



Individual Gross and Microscopic Observations			
HSRL	Study: 43166	Printed: 07/24/2017 08:52:57 AM Prisma3: Version 6.4.0 Build 86.HSRL01	
Rat Sprague-Dawley	Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS	Test Article: Soy Leghemoglobin Preparation	28 Day: Dietary
Animal #: 7007	Group: 1	Day Of Death: Dosing Phase, Day 29	
	Sex: M	Death Status: Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
The following tissues are within normal limits both grossly and microscopically:			Continued from previous page ...
Spleen	Stomach	Testes	Thymus
Trachea	Urinary Bladder		Thyroid Gland

Individual Gross and Microscopic Observations			
HSRL	Study: 43166	Printed: 07/24/2017 08:52:57 AM	
Rat/Sprague-Dawley	Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS	Pristine® Version 6.4.0 Build 86.HSRL01	
Animal #: 7008	Test Article: Soy Leghemoglobin Preparation	28 Day/Dietary	
Group: 1	Sex: M	Day Of Death: Dosing Phase, Day 29	Death Status: Terminal sacrifice
Tissue	Gross Observations/Comments	Status	Microscope Observations/Comments
Kidneys	No Gross Observations		Infiltration, mononuclear cell, interstitial, minimal, focal
Parathyroid Glands	No Gross Observations		One of the pair is Missing Within Normal Limits

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Colon	Duodenum	Epididymides	Esophagus
Eyes	Femur	Harderian glands	Heart	Intestine
Jejunum	Larynx	Liver	Lungs	Lymph Node, Mandibular
Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Pancreas
Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	Pituitary Gland
Prostate Gland	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular
Seminal Vesicles	Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar
Spinal Cord, Midthoracic	Spleen	Sternum	Stomach	Testes
Thymus	Thyroid Gland	Trachea	Urinary Bladder	

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:52:57 AM  
 Study: 43166 Prisma3 Version 6.1.0 Build 86.HSRL01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day: Dietary  
 Animal #: 7009 Group: 1 Day Of Death: Dosing Phase, Day 29

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Eyes	No Gross Observations		Rosettes, retina, minimal, focal
Heart	No Gross Observations		Infiltration, mononuclear cell, minimal, focal
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal
Mammary Gland	No Gross Observations		Atrophy, minimal, multifocal
Parathyroid Glands	No Gross Observations		One of the pair is Missing Within Normal Limits
Prostate Gland	No Gross Observations		Infiltration, mononuclear cell, minimal, multifocal Secretion, decreased amount, minimal /Comments: Ventral prostate affected

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Spleen	Brain
Cecum	Colon	Duodenum	Epididymides	Esophagus
Femur	Harderian glands	Heart	Jejunum	Kidneys
Larynx	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric	Nose and Nasal Turbinates
Optic Nerves	Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches

Individual Gross and Microscopic Observations				Printed: 07/24/2017 08:52:57 AM	
HSRL		Study: 43166		Prisma 7, Version 6.4.0 Build 86.HSRL01	
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS					
Rat Sprague-Dawley		Text Article: Soy Leghemoglobin Preparation		28 Day/Dietary	
Animal #: 7009		Group: 1		Day Of Death: Dosing Phase, Day 29	
		Sex: M		Death Status: Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments		
Continued from previous page ...					
The following tissues are within normal limits both grossly and microscopically.					
Pharynx	Pituitary Gland	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	
Salivary gland, Submandibular	Seminal Vesicles	Skeletal Muscle	Skin	Spinal Cord, Cervical	
Spinal Cord, Lumbar	Spinal Cord, Midthoracic	Spleen	Sternum	Stomach	
Testes	Thymus	Thyroid Gland	Trachea	Urinary Bladder	

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:52:57 AM  
 Study: 43166 Prisma7: Version 0.1.0 Build 86 HSRL01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day: Dietary  
 Animal #: 7010 Group: 1 Day Of Death: Dosing Phase, Day 29  
 Sex: M Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Epididymides	No Gross Observations		Granuloma, sperm, minimal, focal, unilateral
Hardenian glands	No Gross Observations		Dilation, gland, minimal, focal
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal
Thymus	No Gross Observations		Increased number, macrophages, tingible body, minimal, diffuse

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues.

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Colon	Diaphragm	Esophagus	Eyes
Femur	Heart	Intest	Jejunum	Kidneys
Larynx	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric	Mammary Gland
Nose and Nasal Turbinates	Optic Nerves	Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)
Peyer's Patches	Pharynx	Pituitary Gland	Prostate Gland	Rectum
Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	Seminal Vesicles	Skeletal Muscle
Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic	Spleen

**Individual Gross and Microscopic Observations**

Printed: 07/24/2017 08:52:57 AM  
Prisma # Version 6.40 Build 86.HSRL01

HSRL Study: 43166  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary

Rat/Sprague-Dawley  
 Animal #: 7010 Group: 1 Day Of Death: Dosing Phase, Day 29  
 Sex: M Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Continued from previous page ...			
The following tissues are within normal limits both grossly and microscopically:			
Serum	Stomach	Testes	Thyroid Gland
Urinary Bladder			Trachea

Individual Gross and Microscopic Observations				
HSRL	Study: 43166			Printed: 07/21/2017 08:52:57 AM
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS				
Rat/Sprague-Dawley	Test Article: Soy Leghemoglobin Preparation			Prismax Version 6.1.0 Build 86.HSRL91
Animal #: 7011	Group: 1	Day Of Death:	Dosing Phase:	28 Day Dietary
	Sex: F	Day Of Death:	Dosing Phase, Day 30	
		Death Status:	Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
Kidneys	No Gross Observations		Infiltration, mononuclear cell, interstitial, minimal, multifocal Basophilic tubules, minimal, focal	
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal	
Lungs	No Gross Observations		Infiltration, mononuclear cell, minimal, focal	
Parathyroid Glands	No Gross Observations		Both Missing	
Vagina	No Gross Observations		Metestrus, present	
The following protocol-specified required tissues were not examined microscopically:				
Parathyroid Glands				
The following tissues are within normal limits both grossly and microscopically				
Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Cervix	Colon	Duodenum	Esophagus
Eyes	Femur	Harderian glands	Heart	Ileum
Ileum	Larynx	Lymph Node, Mandibular	Lymph Node, Mesenteric	Mammary Gland
Nose and Nasal Turbinates	Optic Nerves	Ovaries	Oviducts	Pancreas
Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	Pituitary Gland	Rectum
Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	Skeletal Muscle	Skin

Individual Gross and Microscopic Observations					Printed: 07/24/2017 08:52:57 AM
HSRL		Study: 43166		Picoma7: Version 6.4.0 Build 86.HSRL01	
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS					
Test Article: Soy Leghemoglobin Preparation					28 Day/Dietary
Rat Sprague-Dawley	Group: 1	Day Of Death: Dosing Phase, Day 30			
Animal #: 7011	Sex: F	Death Status: Terminal sacrifice			
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments		
					Continued from previous page ...
The following tissues are within normal limits both grossly and microscopically:					
Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic	Spleen	Stomach	
Stomach	Thymus	Thyroid Gland	Trachea	Urinary Bladder	
Uterus					



**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:52:57 AM  
 Study: 43166 Prismox Version 6.4.0 Build 86.HSRL01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat: Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
 Animal #: 7012 Group: 1 Day Of Death: Dosing Phase, Day 30  
Sex: F Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Kidneys	No Gross Observations		Infiltration, mononuclear cell, interstitial, minimal, multifocal
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal
Parathyroid Glands	No Gross Observations		One of the pair is Missing Within Normal Limits
Vagina	No Gross Observations		Proestrus, present

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits, both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Spleen	Brain
Cecum	Cervix	Colon	Duodenum	Esophagus
Eyes	Femur	Hartman glands	Heart	Intest
Jejunum	Larynx	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric
Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Ovaries	Oviducts
Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx
Pituitary Gland	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular
Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic

Individual Gross and Microscopic Observations				Printed: 07/24/2017 08:52:57 AM
HSRL		Study: 43166		Pristima® Version 6.40 Build 86 HSR1.01
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS				
Rat/Sprague-Dawley		Test Article: Soy Leghemoglobin Preparation		28 Day/Dietary
Animal #: 7012	Group: 1	Day Of Death:	Dosing Phase, Day 30	
	Sex: F	Death Status: Terminal sacrifice		
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
Continued from previous page ...				
The following tissues are within normal limits both grossly and microscopically:				
Spleen	Sternum	Stomach	Thymus	Thyroid Gland
Trachea	Urinary Bladder	Uterus		

Individual Gross and Microscopic Observations				Printed: 07/24/2017 08:52:57 AM	
HSRL	Study: 43166		Prisma3: Version 6.10 Build 86 HSRL01		
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS					
Rat/Sprague-Dawley	Test Article: Soy Leghemoglobin Preparation		28 Day/Dietary		
Animal #: 7013	Group: 1	Day Of Death: Dosing Phase, Day 30			
Sex: F			Death Status: Terminal sacrifice		
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments		
Harderian glands	No Gross Observations		Infiltration, mononuclear cell, minimal, focal		
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal		
Optic Nerves	No Gross Observations		Tissue Comment: Two optic nerves available for evaluation		
Thymus	No Gross Observations		Increased number, macrophages, tingible body, minimal, diffuse		
Uterus	Fluid filled, Noted Fluid filled, Noted	Correlated Correlated	Vagina, Estrus, present Dilation, mild		
Vagina	No Gross Observations		Estrus, present		
The following protocol-specified required tissues were not examined microscopically: There are no such tissues					
The following tissues are within normal limits both grossly and microscopically					
Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Stomach	Brain	
Cecum	Cervix	Colon	Duodenum	Esophagus	
Eyes	Femur	Heart	Ileum	Jejunum	
Kidneys	Larynx	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric	
Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Ovaries	Oviducts	

Individual Gross and Microscopic Observations				Printed: 07/24/2017 08:52:57 AM	
HSRL		Study: 43166		Pristima® Version 6.4.0 Build 86.HSRL01	
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS					
Test Article: Soy Leghemoglobin Preparation					
Rat: Sprague-Dawley	Group: 1	Day Of Death:	Dosing Phase:	28 Day: Dietary	
Animal #: 7013	Sex: F	Death Status:		Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments		
Continued from previous page ...					
The following tissues are within normal limits both grossly and microscopically:					
Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	
Pituitary Gland	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	
Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic	
Spleen	Sternum	Stomach	Thyroid Gland	Trachea	
Urinary Bladder					

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:52:57 AM  
 Study: 43166 Pristima 8, Version 6.4.0 Build 86 HSRL01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
 Animal #: 7014 Group: 1 Day Of Death: Dosing Phase, Day 30  
 Sex: F Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Kidneys	No Gross Observations		Basophilia, tubules, minimal, focal Dilation, tubules, minimal, focal Infiltration, mononuclear cell, interstitial, minimal, multifocal
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal
Peyer's Patches	No Gross Observations		Mineralization, minimal, multifocal
Thymus	No Gross Observations		Increased number, macrophages, tingible body, minimal, diffuse
Vagina	No Gross Observations		Metestrus, present

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Spleen	Brain
Cecum	Cervix	Colon	Duodenum	Esophagus
Eyes	Femur	Hankian glands	Heart	Intest
Jejunum	Larynx	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric
Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Ovaries	Oviducts
Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)	Pharynx	Pituitary Gland

Individual Gross and Microscopic Observations				Printed: 07/24/2017 08:52:57 AM
HSRL	Study: 43166			Prismus® Version 6.10 Build 86 HSRL01
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS				
Rat/Sprague-Dawley	Test Article: Soy Leghemoglobin Preparation			28 Day/Dietary
Animal #: 7013	Group: 1	Day Of Death:	Dosing Phase, Day 30	
	Sex: F	Death Status: Terminal sacrifice		
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
Continued from previous page ...				
The following tissues are within normal limits both grossly and microscopically:				
Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	Skeletal Muscle
Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic	Spleen
Sternum	Stomach	Thyroid Gland	Trachea	Urinary Bladder
Uterus				

Individual Gross and Microscopic Observations				Printed: 07/24/2017 08:52:57 AM	
HSRL		Study: 43166		Prisma7: Version 6.4.0 Build 86.HSRL01	
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS					
Test Article: Soy Leghemoglobin Preparation					
Rat Sprague-Dawley	Group: 1	Day Of Death: Dosing Phase, Day 30		28 Day Dietary	
Animal #: 7015	Sex: F	Death Status: Terminal sacrifice			
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments		
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal		
Parathyroid Glands	No Gross Observations		One of the pair is Missing Within Normal Limits		
Salivary Gland, Parotid	No Gross Observations		Infiltration, mononuclear cell, minimal, focal		
Thyroid	No Gross Observations		Increased number, macrophages, tingible body, minimal, diffuse		
Vagina	No Gross Observations		Proestrus, present		
The following protocol-specified required tissues were not examined microscopically: There are no such tissues					
The following tissues are within normal limits both grossly and microscopically:					
Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain	
Cecum	Cervix	Colon	Diaphragm	Esophagus	
Eyes	Femur	Harderian glands	Heart	Heart	
Jejunum	Kidneys	Larynx	Lungs	Lymph Node, Mandibular	
Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Ovaries	
Oviducts	Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	
Pharynx	Pituitary Gland	Rectum	Salivary Gland, Sublingual	Salivary gland, Submandibular	

Individual Gross and Microscopic Observations  
 Study: 43166  
 Printed: 07/24/2017 08:52:57 AM  
 HSRL  
 Prisma® Version 6.40 Build 86.HSRL01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Test Article: Soy Leghemoglobin Preparation  
 Rat Sprague-Dawley  
 Animal #: 7015  
 Group: 1  
 Sex: F  
 Day Of Death: 28 Day/Dietary  
 Death Status: Terminal sacrifice  
 Design Phase: Day 30

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
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The following tissues are within normal limits both grossly and microscopically:

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic
Spleen	Sternum	Stomach	Thyroid Gland	Trachea
Urinary Bladder	Uterus			

Continued from previous page ...



Individual Gross and Microscopic Observations				Printed: 07/24/2017 08:52:57 AM	
HSRL		Study: 43166		Prisma8: Version 6.40 Build 86.HSRL01	
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS					
Rat: Sprague-Dawley		Test Article: Soy Leghemoglobin Preparation		28 Day: Dietary	
Animal #: 7016		Group: I		Day Of Death: Dosing Phase, Day 30	
		Sex: F		Death Status: Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments		
Hardenian glands	No Gross Observations		Infiltration, mononuclear cell, minimal, focal		
Kidneys	No Gross Observations		Basophilia, tubules, minimal, focal		
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal		
Thymus	No Gross Observations		Increased number, macrophages, tingible body, minimal, focal		
Vagina	No Gross Observations		Metestrus, present		
The following protocol-specified required tissues were not examined microscopically: There are no such tissues					
The following tissues are within normal limits both grossly and microscopically					
Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain	
Cecum	Cervix	Colon	Duodenum	Esophagus	
Eyes	Femur	Heart	Ileum	Jejunum	
Larynx	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric	Mammary Gland	
Nose and Nasal Turbinates	Optic Nerves	Ovaries	Oviducts	Pancreas	
Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	Pituitary Gland	
Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	Skeletal Muscle	

Individual Gross and Microscopic Observations					Printed: 07/24/2017 08:52:57 AM
HSRL		Study: 43166		Pristima® Version 6.10 Build 86.HSRL01	
Rat: Sprague-Dawley		Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS			28 Day/Dietary
Animal #: 7016		Test Article: Soy Leghemoglobin Preparation		Day Of Death: Design Phase, Day 30	
		Group: 1		Day Of Death: Design Phase, Day 30	
		Sex: F		Death Status: Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments		
The following tissues are within normal limits both grossly and microscopically:					Continued from previous page ...
Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic	Spleen	
Sternum	Stomach	Thyroid Gland	Trachea	Urinary Bladder	
Uterus					

Individual Gross and Microscopic Observations				Printed: 07/24/2017 08:52:57 AM	
HSRL	Study: 43166		Prisma3, Version 6.10 Build 86.HSRL01		
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS		Test Article: Soy Leghemoglobin Preparation		28 Day/Dietary	
Rat: Sprague-Dawley	Group: 1	Day Of Death: Dosing Phase, Day 30			
Animal #: 7017	Sex: F	Death Status: Terminal sacrifice			
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments		
Heart	No Gross Observations		Infiltration, mononuclear cell, minimal, focal		
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal		
Pituitary Gland	No Gross Observations		Cyst(s), pars distalis, minimal, multifocal		
Uterus	Fluid filled, Noted Fluid filled, Noted	Correlated Correlated	Vagina, Estrus, present Dilation, mild		
Vagina	No Gross Observations		Estrus, present		
The following protocol-specified required tissues were not examined microscopically: There are no such tissues					
The following tissues are within normal limits both grossly and microscopically:					
Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain	
Cecum	Cervix	Colon	Duodenum	Esophagus	
Eyes	Femur	Harderian glands	Ileum	Jejunum	
Kidneys	Larynx	Lungs	Lymph Node, Mandibular	Lymph Node, Mesentene	
Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Ovaries	Oviducts	
Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	
Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	Skeletal Muscle	

Individual Gross and Microscopic Observations				
HSRL		Study: 43166	Printed: 07/24/2017 08:52:57 AM	
		StudyTitle: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS	Pristima® Version 6.4.0 Build 86.HSRL01	
Rat:Sprague-Dawley		Test Article: Soy Leghemoglobin Preparation	28 Day/Dietary	
Animal #: 7017	Group: 1	Day Of Death:	Dosing Phase, Day 30	
	Sex: F	Death Status:	Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
Continued from previous page ...				
The following tissues are within normal limits both grossly and microscopically:				
Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic	Spleen
Serum	Stomach	Thymus	Thyroid Gland	Trachea
Urinary Bladder				

Individual Gross and Microscopic Observations				Printed: 07/24/2017 08:52:57 AM	
HSRL	Study: 43166		Prisma7, Version 6.10 Build 86.HSRL01		
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS					
Rat Sprague-Dawley	Test Article: Soy Leghemoglobin Preparation		Day Of Death: Dosing Phase, Day 30		28 Day: Dietary
Animal #: 7018	Group: 1	Sex: F		Death Status: Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments		
Eyes	No Gross Observations		Rosettes, retina, minimal, focal		
Harderian glands	No Gross Observations		Infiltration, mononuclear cell, minimal, focal		
Heart	No Gross Observations		Infiltration, mononuclear cell, minimal, focal		
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal		
Pituitary Gland	No Gross Observations		Cyst(s), pars distalis, minimal, multifocal		
Uterus	Fluid filled, Noted	Correlated	Vagina, Estrus, present		
	Fluid filled, Noted	Correlated	Dilation, mild		
Vagina	No Gross Observations		Estrus, present		
The following protocol-specified required tissues were not examined microscopically: There are no such tissues					
The following tissues are within normal limits both grossly and microscopically:					
Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain	
Cecum	Cervix	Colon	Duodenum	Esophagus	
Femur	Ileum	Jejunum	Kidneys	Larynx	
Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates	
Optic Nerves	Ovaries	Oviducts	Pancreas	Parathyroid Glands	

Individual Gross and Microscopic Observations				
HSRL		Study: 43166		Printed: 07/24/2017 08:52:57 AM
Rat Sprague-Dawley		Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS		Pristima* Version 6.10 Build 86.HSRL01
Animal #: 7018	Group: 1	Test Article: Soy Leghemoglobin Preparation	Day Of Death: Dosing Phase, Day 30	28 Day/Dietary
	Sex: F		Death Status: Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
The following tissues are within normal limits both grossly and microscopically:				
Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	Rectum	Salivary Gland, Parotid
Salivary Gland, Sublingual	Salivary gland, Submandibular	Skeletal Muscle	Skin	Spinal Cord, Cervical
Spinal Cord, Lumbar	Spinal Cord, Midthoracic	Spleen	Sternum	Stomach
Thymus	Thyroid Gland	Trachea	Urinary Bladder	

Continued from previous page ...

Individual Gross and Microscopic Observations			
HSRL	Study: 43166	Printed: 07/24/2017 08:52:57 AM	
Rat: Sprague-Dawley	Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS	Pristima 3, Version 6.10 Build 86.HSRL01	
Animal #: 7019	Test Article: Soy Leghemoglobin Preparation	Day Of Death:	Dosing Phase, Day 30
Group: 1	Sex: F	28 Day Dietary	
		Death Status: Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal
Vagina	No Gross Observations		Metestrus, present

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues.

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Cervix	COLON	Duodenum	Esophagus
Eyes	Femur	Harderian glands	Heart	Humi
Jejunum	Kidneys	Larynx	Lungs	Lymph Node, Mandibular
Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Ovaries
Oviducts	Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches
Pharynx	Pituitary Gland	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual
Salivary gland, Submandibular	Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar
Spinal Cord, Midthoracic	Spleen	Sternum	Stomach	Thymus
Thyroid Gland	Trachea	Urinary Bladder	Uterus	

Individual Gross and Microscopic Observations				
HSRL	Study: 43166			Printed: 07/24/2017 08:52:57 AM
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS				
Test Article: Soy Leghemoglobin Preparation				
Rat/Sprague-Dawley	Group: 1	Day Of Death:	Dosing Phase, Day 30	28 Day/Dietary
Animal #: 7020	Sex: F	Death Status: Terminal sacrifice		
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
Heart	No Gross Observations		Infiltration, mononuclear cell, minimal, focal	
Kidneys	No Gross Observations		Basophilic, tubules, minimal, focal	
Mammary Gland	No Gross Observations		Dilation, duct(s), mild, focal, lactiferous duct	
Uterus	Fluid filled, Noted	Correlated	Dilation, moderate	
	Fluid filled, Noted	Correlated	Vagina, Estrus, present	
Vagina	No Gross Observations		Estrus, present	
The following protocol-specified required tissues were not examined microscopically:				
There are no such tissues				
The following tissues are within normal limits both grossly and microscopically:				
Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Stomach	Brain
Cecum	Cervix	Colon	Duodenum	Esophagus
Eyes	Femur	Harderian glands	Ileum	Jejunum
Larynx	Liver	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric
Nose and Nasal Turbinates	Optic Nerves	Ovaries	Oviducts	Pancreas
Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	Pituitary Gland
Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	Skeletal Muscle



**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:52:57 AM  
 Study: 43166 Prisma3: Version 6.4.0 Build 86.HSRL01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat/Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day Dietary  
 Animal #: 7020 Group: 1 Day Of Death: Dosing Phase, Day 30  
Sex: F Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
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Continued from previous page ...

The following tissues are within normal limits both grossly and microscopically:

Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic	Spleen
Sternum	Stomach	Thymus	Thyroid Gland	Trachea
Urinary Bladder				

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:54:38 AM  
 Study: J3166 Pristima® Version 6.4.0 Build 86.HSRL01

Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat/Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
 Animal #: 7031 Group: 2 Day Of Death: Dosing Phase, Day 30  
Sex: F Death Status: Terminal sacrifice

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Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Vagina	No Gross Observations		Diestrus, present

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues

The following tissues are within normal limits both grossly and microscopically:  
 Cervix Ovaries Oviducts Uterus

**Individual Gross and Microscopic Observations**

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 Prisma# Version 6.10 Build 86 HSRL01

HSRL  
 Study: 43166  
 StudyTitle: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Test Article: Soy Leghemoglobin Preparation  
 28 Day/Dietary

Rat Sprague-Dawley  
 Animal #: 7032  
 Group: 2  
 Day Of Death: Dosing Phase, Day 30  
 Sex: F  
 Death Status: Terminal sacrifice

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Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Vagina	No Gross Observations		Estrus, present

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues

The following tissues are within normal limits both grossly and microscopically:  
 Cervix                      Ovaries                      Oviducts                      Uterus

**Individual Gross and Microscopic Observations**

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 Pictima® Version 6.4.0 Build 86.HSRL01

HSRL Study: 43166  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
 Animal #: 7033 Group: 2 Sex: F Day Of Death: Death Phase, Day 30 Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Vagina	No Gross Observations		Metestrus, present

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues

The following tissues are within normal limits both grossly and microscopically:  
 Cervix Ovaries Oviducts Uterus

Individual Gross and Microscopic Observations			
HSRL	Study: 43166	Printed: 07/24/2017 08:54:38 AM	
	Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS	Prisma3 - Version 6.4.0 Build 86.HSRL01	
Rat Sprague-Dawley	Test Article: Soy Leghemoglobin Preparation	Day Of Death: Dosing Phase, Day 30	28 Day: Dietary
Animal #: 7034	Group: 2	Sex: F	Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Vagina	No Gross Observations		Tissue Comment: Only cervix and scunt vagina present Metestrus, present

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues

The following tissues are within normal limits both grossly and microscopically:  
 Cervix                      Ovaries                      Oviducts                      Uterus

**Individual Gross and Microscopic Observations**

Printed: 07/24/2017 08:54:38 AM  
 Prisma3 Version 6.10 Build 86.HSRL01

HSRL Study: 43166  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary

Rat/Sprague-Dawley  
 Animal #: 7035 Group: 2 Day Of Death: Dosing Phase, Day 30  
 Sex: F Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Vagina	No Gross Observations		Metestrus, present

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues

The following tissues are within normal limits both grossly and microscopically:  
 Cervix Ovaries Oviducts Uterus

**Individual Gross and Microscopic Observations**

Printed: 07/24/2017 08:54:38 AM  
 Prisma3: Version 6.4.0 Build 86.HSRL01

HSRL Study: 43166  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Prisma3: Version 6.4.0 Build 86.HSRL01

Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
 Animal #: 7036 Group: 2 Day Of Death: Dosing Phase, Day 30  
 Sex: F Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscope Observations/Comments
Vagina	No Gross Observations		Tissue Comment: Vagina present for evaluation. Metestrus, present

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues

The following tissues are within normal limits both grossly and microscopically:  
 Cervix Ovaries Oviducts Uterus

**Individual Gross and Microscopic Observations**

Printed: 07/24/2017 08:54:38 AM  
 PrismaX Version 6.40 Build 86.HSRL01

HSRL Study: 43166  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 PrismaX Version 6.40 Build 86.HSRL01

Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
 Animal #: 7037 Group: 2 Day Of Death: Dosing Phase, Day 30

Sex: F Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Vagina	No Gross Observations		Tissue Comment: Only cervix and scant vagina present. Metastasis, present

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues

The following tissues are within normal limits both grossly and microscopically:  
 Cervix Ovaries Oviducts Uterus



Individual Gross and Microscopic Observations			
HSRL	Study: 43166	Printed: 07/24/2017 08:54:38 AM	
	Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS	Pristima® Version 6.40 Build 86.HSRL01	
Rat: Sprague-Dawley	Test Article: Soy Leghemoglobin Preparation	28 Day/Dietary	
Animal #: 7038	Group: 2	Day Of Death: Dosing Phase, Day 50	
	Sex: F	Death Status: Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Vagina	No Gross Observations		Tissue Comment: Only cervix and scant vagina present. Metestrus, present
The following protocol-specified required tissues were not examined microscopically: There are no such tissues			
The following tissues are within normal limits both grossly and microscopically:			
Cervix	Ovaries	Oviducts	Uterus

**Individual Gross and Microscopic Observations**

Printed: 07/21/2017 08:54:38 AM  
Prism: Version 6.1.0 Build 86.HSRL01

HSRL Study: 43166  
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
Test Article: Soy Leghemoglobin Preparation 28 Day Dietary

Rat Sprague-Dawley  
Animal #: 7039  
Group: 2  
Sex: F  
Day Of Death: Dosing Phase, Day 30  
Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Vagina	No Gross Observations		Metastasis, present

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:  
Cervix                      Ovaries                      Oviducts                      Uterus

**Individual Gross and Microscopic Observations**

Printed: 07/24/2017 08:54:38 AM  
 Prisma® Version 6.4.0 Build 86.HSRL01

HSRL  
 Study: 43166  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Test Article: Soy Leghemoglobin Preparation  
 28 Day Dietary

Rat/Sprague-Dawley  
 Animal #: 7040  
 Group: 2  
 Sex: F  
 Day Of Death: Dosing Phase, Day 30  
 Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Vagina	No Gross Observations		Tissue Comment: Only cervix and scant vagina present. Metestrus, present

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues

The following tissues are within normal limits both grossly and microscopically:  
 Cervix                      Ovaries                      Oviducts                      Uterus

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:55:50 AM  
 Study: 43166 Prisma® Version 6.40 Build 86 HSRL01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat/Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
 Animal #: 7047 Group: 3 Day Of Death: Dosing Phase, Day 29  
Sex: M Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Brain	Depressed Area, focal, on left hemisphere Comments: possible prosection damage	Correlated	Tissue Comment: Artifactual damage to cortex extending into ventricle. Artifact, present

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:  
There are no such tissues

**Individual Gross and Microscopic Observations**

Printed: 07/24/2017 08:55:50 AM

HSRL Study: 43166 Prisma 3: Version 6.4.0 Build 86.HSRL.01

Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day Dietary

Animal #: 7051 Group: 3 Day Of Death: Dosing Phase, Day 30

Sex: F Death Status: Terminal sacrifice

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Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Vagina	No Gross Observations		Diestrus, present

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues.

The following tissues are within normal limits both grossly and microscopically:

Cervix	Ovaries	Oviducts	Uterus
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**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:55:50 AM  
 Study: 43166 Prisma® Version 6.4.0 Build 86 HSR1.01

Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS

Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
 Animal #: 7052 Group: J Day Of Death: Dosing Phase, Day 30

Sex: F Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscope Observations/Comments
Vagina	No Gross Observations		Tissue Comment: Only cervix and scant vagina present. Preestrus, present

The following, protocol-specified required tissues were not examined microscopically:  
 There are no such tissues

The following tissues are within normal limits both grossly and microscopically:  
 Cervix                      Ovaries                      Oviducts                      Uterus

Individual Gross and Microscopic Observations

Printed: 07/24/2017 08:55:50 AM

HSRL Study: 43166 Prisma3 Version 6.4.0 Build 86.HSRL01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
 Animal #: 7053 Group: 3 Sex: F Day Of Death: Dosing Phase, Day 30 Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Uterus	Fluid filled, Noted Fluid filled, Noted	Correlated Correlated	Dilation, moderate Vagina, Estrus, present
Vagina	No Gross Observations		Estrus, present

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues.

The following tissues are within normal limits both grossly and microscopically:  
 Cervix Ovaries Oviducts

**Individual Gross and Microscopic Observations**

Printed: 07/24/2017 08:55:50 AM  
 Prisma® Version 6.4.0 Build 86.HSRL01

HSRL  
 Study: 43166  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat: Sprague-Dawley  
 Animal #: 7054  
 Test Article: Soy Leghemoglobin Preparation  
 Group: 3  
 Sex: F  
 Day Of Death: Dosing Phase, Day 30  
 Death Status: Terminal sacrifice  
 28 Day: Dietary

Tissue	Gross Observations/Comments	Status	Microscope Observations/Comments
Vagina	No Gross Observations		Diestrus, present

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues

The following tissues are within normal limits both grossly and microscopically:  
 Cervix                      Ovaries                      Oviducts                      Uterus



Individual Gross and Microscopic Observations			
HSRL	Study: 43166	Printed: 07/24/2017 08:55:50 AM	
	StudyTitle: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS	Prisma3: Version 6.10 Build 86.HSRL01	
Rat/Sprague-Dawley	Test Article: Soy Leghemoglobin Preparation	28 Day/Dietary	
Animal #: 7055	Group: 3	Day Of Death: Dosing Phase, Day 30	
	Sex: F	Death Status: Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Spleen	Stricture, Noted	Not Concluded	Within Normal Limits
Vagina	No Gross Observations		Tissue Comment: Only cervix and scant vagina present. Estrus, present
The following protocol-specified required tissues were not examined microscopically: There are no such tissues			
The following tissues are within normal limits both grossly and microscopically:			
Cervix	Ovaries	Oviducts	Uterus

**Individual Gross and Microscopic Observations**

Printed: 07/24/2017 08:55:50 AM  
 Prisma® Version 6.4.0 Build 86.HSRL01

HSRL Study: 43166  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Test Article: Soy Leghemoglobin Preparation 28 Day Dietary

Rat/Sprague-Dawley  
 Animal #: 7056  
 Group: 3  
 Sex: F  
 Day Of Death: Dosing Phase, Day 30  
 Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscope Observations/Comments
Vagina	No Gross Observations		Tissue Comment: Only cervix and scant vagina present. Distrus, present

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues

The following tissues are within normal limits both grossly and microscopically:  
 Cervix                      Ovaries                      Oviducts                      Uterus

**Individual Gross and Microscopic Observations**

Printed: 07/24/2017 08:55:50 AM  
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HSRL Study: 43166  
 StudyTitle: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Prisma#: Version 6.10 Build 86.HSRL01

Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
 Animal #: 7057 Group: 3 Day Of Death: Dosing Phase, Day 30

Sex: F Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Vagina	No Gross Observations		Metestrus, present

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues.

The following tissues are within normal limits both grossly and microscopically:  
 Cervix Ovaries Oviducts Uterus

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:55:50 AM  
 Study: 43166 Protocol#: Version 6.4.0 Build 86.HSRL01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat: Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day: Dietary  
 Animal #: 7058 Group: J Day Of Death: Dosing Phase, Day 30  
Sex: F Death Status: Terminal sacrifice

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Tissue	Gross Observations/Comments	Status	Microscope Observation/Comments
Vagina	No Gross Observations		Metestrus, present

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues

The following tissues are within normal limits both grossly and microscopically:  
 Cervix                      Ovaries                      Oviducts                      Uterus

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:55:50 AM  
Prisma3: Version 6.4.0 Build 86.HSRL01  
 Study: 43166  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day: Dietary  
 Animal #: 7059 Group: 3 Day Of Death: Dosing Phase, Day 30  
Sex: F Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observation/Comments
Uterus	No Gross Observations		Dilation, mild
Vagina	No Gross Observations		Proestrus, present

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues

The following tissues are within normal limits both grossly and microscopically:  
 Cervix                      Ovaries                      Oviducts

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:50:36 AM  
 Study: 43166 Pristima® Version 6.10 Build 86 HSRL01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat: Sprague-Dawley Test Article: Soy Leghemoglobin Preparation  
 Animal #: 7061 Group: 4 Day Of Death: Dosing Phase, Day 29 28 Day/Dietary  
 Sex: M Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal Vacuolation, hepatocellular, NOS, minimal, diffuse
Thymus	No Gross Observations		Increased number, macrophages, tingible body, minimal, diffuse

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Colon	Duodenum	Epididymides	Esophagus
Eyes	Femur	Harderian glands	Heart	Ileum
Jejunum	Kidneys	Larynx	Lungs	Lymph Node, Mandibular
Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Pancreas
Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	Pituitary Gland
Prostate Gland	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular
Seminal Vesicles	Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar
Spinal Cord, Midthoracic	Spleen	Sternum	Stomach	Testes
Thyroid Gland	Trachea	Urinary Bladder		

Individual Gross and Microscopic Observations			
HSRL	Study: 43166	Printed: 07/24/2017 08:56:36 AM	
Rat/Sprague-Dawley	StudyTitle: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS	Pristima® Version 6.4.0 Build 86.HSRL.01	
Animal #: 7062	Test Article: Soy Leghemoglobin Preparation	Day Of Death: Dosing Phase, Day 29	28 Day/Dietary
	Group: 4		
	Sex: M	Death Status: Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal
Thymus	No Gross Observations		Increased number, macrophages, tingible body, minimal, diffuse

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	COLON	Duodenum	Epididymides	Esophagus
Eyes	Femur	Harderian glands	Heart	Heam
Jejunum	Kidneys	Larynx	Lungs	Lymph Node, Mandibular
Lymph Neck, Mesenteric	Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Pancreas
Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	Pituitary Gland
Prostate Gland	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular
Seminal Vesicles	Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar
Spinal Cord, Midthoracic	Spleen	Sternum	Stomach	Testes
Thyroid Gland	Trachea	Urinary Bladder		

Individual Gross and Microscopic Observations				Printed: 07/24/2017 08:56:36 AM	
HSRL		Study: 43166		Prisma7: Version 6.4.0 Build 86.HSRL01	
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS					
Rat Sprague-Dawley		Test Article: Soy Leghemoglobin Preparation		28 Day/Dietary	
Animal #: 7063		Group: 4		Day Of Death: Dosing Phase, Day 29	
		Sex: M		Death Status: Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments		
Larynx	No Gross Observations		Infiltration, mononuclear cell, minimal, focal		
Liver	No Gross Observations		Vacuolation, hepatocellular, NOS, minimal, diffuse Infiltration, mixed cell, minimal, focal		
Parathyroid Glands	No Gross Observations		Within Normal Limits One of the pair is Missing		

The following, protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Colon	Duodenum	Epididymides	Esophagus
Eyes	Femur	Harderian glands	Heart	Intest
Jejunum	Kidneys	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric
Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Pancreas	Parathyroid Glands
Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	Pituitary Gland	Prostate Gland
Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	Seminal Vesicles
Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic



Individual Gross and Microscopic Observations				Printed: 07/24/2017 08:56:36 AM	
HSRL		Study: 43166		Prismosoft Version 6.40 Build 86.HSRL.01	
Rat Sprague-Dawley		Study Title: SOY LEGHEMOGLOBIN PREPARATION, A 28-DAY DIETARY STUDY IN RATS		28 Day: Dietary	
Animal #: 7063		Test Article: Soy Leghemoglobin Preparation		Day Of Death: Dosing Phase, Day 29	
		Group: 4		Death Status: Terminal sacrifice	
		Sex: M			
Tissue	Gross Observations/Comments	Status	Microscope Observations/Comments		
Continued from previous page ...					
The following tissues are within normal limits both grossly and microscopically.					
Spleen	Sternum	Stomach	Testes	Thymus	
Thyroid Gland	Trachea	Urinary Bladder			

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:56:36 AM  
 Study: 43166 Prisma® Version 6.4.0 Build R6.HSRL01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat/Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day Dietary  
 Animal #: 7064 Group: 4 Day Of Death: Dosing Phase, Day 29  
 Sex: M Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Epididymides	No Gross Observations		Debris, cellular, luminal, minimal, diffuse
Eyes	No Gross Observations		Rosettes, retina, minimal, focal
Kidneys	No Gross Observations		Basophilic tubules, minimal, focal
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal
Parathyroid Glands	No Gross Observations		One of the pair is Missing Within Normal Limits
Testes	No Gross Observations		Atrophy, tubules, minimal, focal Vacuolation, Sertoli cells, minimal, multifocal
Thymus	No Gross Observations		Increased number, macrophages, tingible body, minimal, diffuse

The following protocol-specified required tissues were not examined microscopically:  
 There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Stomach	Brain
Cecum	Colon	Duodenum	Esophagus	Femur
Harderian glands	Heart	Ileum	Jejunum	Larynx
Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:56:36 AM  
 Study: 43166 Prisma3: Version 6.10 Build 86.HSRI.01  
 StudyTitle: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
 Animal #: 7064 Group: 4 Day Of Death: Dosing Phase, Day 29  
 Sex: M Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Continued from previous page ...			
The following tissues are within normal limits both grossly and microscopically:			
Optic Nerves	Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)
Pharynx	Pituitary Gland	Prostate Gland	Rectum
Salivary Gland, Sublingual	Salivary gland, Submandibular	Seminal Vesicles	Skeletal Muscle
Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic	Spleen
Stomach	Thyroid Gland	Trachea	Urinary Bladder
			Peyer's Patches
			Salivary Gland, Parotid
			Skin
			Stemum

Individual Gross and Microscopic Observations			
HSRL	Study: 43166	Printed: 07/21/2017 08:50:36 AM	
Rat Sprague-Dawley	Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS	Prisma® Version 6.4.0 Build 86.HSRL01	
Animal #: 7065	Test Article: Soy Leghemoglobin Preparation	Day Of Death: Dosing Phase, Day 29	28 Day: Dietary
	Group: 4	Sex: M	Death Status: Terminal sacrifice
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal
Thymus	No Gross Observations		Increased number, macrophages, trigable body, minimal, diffuse

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Colon	Duodenum	Epididymides	Esophagus
Eyes	Femur	Harderian glands	Heart	Ileum
Jejunum	Kidneys	Larynx	Lungs	Lymph Node, Mandibular
Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Pancreas
Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	Pituitary Gland
Prostate Gland	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular
Seminal Vesicles	Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar
Spinal Cord, Midthoracic	Spleen	Sternum	Stomach	Testes
Thyroid Gland	Trachea	Urinary Bladder		

**Individual Gross and Microscopic Observations**

Printed: 07/24/2017 08:56:36 AM  
Prisma3, Version 6.4.0 Build 86-HSRL01

HSRL Study: 43166  
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day Dietary  
Animal #: 7066 Group: 4 Sex: M Day Of Death: Dosing Phase, Day 29 Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Epididymids	No Gross Observations		Debris, cellular, luminal, minimal, diffuse, bilateral
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal
Parathyroid Glands	No Gross Observations		One of the pair is Missing Within Normal Limits
Testes	No Gross Observations		Decreased number, round spermatis, minimal, multifocal, bilateral
Thymus	No Gross Observations		Increased number, macrophages, fungible body, minimal, multifocal

The following protocol-specified required tissues were not examined microscopically  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aceta	Bone marrow, Femur	Bone Marrow, Spleen	Brain
Cecum	Colon	Duodenum	Esophagus	Eyes
Femur	Harderian glands	Heart	Intestine	Jejunum
Kidneys	Larynx	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric
Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Pancreas	Parathyroid Glands
Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	Pituitary Gland	Prostate Gland

Individual Gross and Microscopic Observations				
HSRL	Study: 43166			Printed: 07/24/2017 08:56:36 AM
Rat Sprague-Dawley	Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS			Pristima Version 6.40 Build 86.HSRL01
Animal #: 7066	Group: 4	Test Article: Soy Leghemoglobin Preparation	Day Of Death: Dosing Phase, Day 29	28 Day Dietary
	Sex: M		Death Status: Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
The following tissues are within normal limits both grossly and microscopically			Continued from previous page ...	
Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	Seminal Vesicles
Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic
Spleen	Sternum	Stomach	Thyroid Gland	Trachea
Urinary Bladder				

Individual Gross and Microscopic Observations			
HSRL	Study: 43166	Printed: 07/24/2017 08:56:36 AM Prisma3 Version 6.10 Build 86.HSRL01	
Rat Sprague-Dawley	Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS	28 Day/Dietary	
Animal #: 7067	Test Article: Soy Leghemoglobin Preparation	Group: 4	Day Of Death: Dosing Phase, Day 29
	Sex: M	Death Status: Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Larynx	No Gross Observations		Infiltration, neutrophil, minimal, focal
Parathyroid Glands	No Gross Observations		Tissue Comment: Two parathyroids available for evaluation

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Colon	Duodenum	Epididymides	Esophagus
Eyes	Femur	Harderian glands	Heart	Ileum
Jejunum	Kidneys	Liver	Lungs	Lymph Node, Mandibular
Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Pancreas
Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	Pituitary Gland
Prostate Gland	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular
Seminal Vesicles	Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar
Spinal Cord, Midthoracic	Spleen	Sternum	Stomach	Testes
Thymus	Thyroid Gland	Trachea	Urinary Bladder	

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:56:36 AM  
 Study: 43166 Pristima#: Version 6.4.0 Build 86.HSR1.01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat: Sprague-Dawley Test Article: Soy Leghemoglobin Preparation  
 Animal #: 7068 Group: 4 Day Of Death: Dosing Phase, Day 29 28 Day/Dietary  
 Sex: M Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Bone marrow, Femur	No Gross Observations		Hypocellularity, minimal, diffuse
Eyes	No Gross Observations		Tissue Comment: One eye or (s) artifactually destroyed
Heart	No Gross Observations		Infiltration, mixed cell, minimal, focal
Kidneys	No Gross Observations		Infiltration, mononuclear cell, interstitial, minimal, multifocal
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal
Parathyroid Glands	No Gross Observations		Within Normal Limits One of the pair is Missing
Prostate Gland	No Gross Observations		Infiltration, mononuclear cell, minimal, multifocal
Thymus	No Gross Observations		Increased number, macrophages, tingible body, minimal, diffuse

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone Marrow, Spleen	Brain	Cecum
Colon	Duodenum	Epididymides	Esophagus	Eyes
Femur	Harderian glands	Ileum	Jejunum	Larynx



**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:50:30 AM  
 Study: 43166 Prisma#: Version 6.4.0 Build 86 HSRL.01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat/Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
 Animal #: 7068 Group: 4 Day Of Death: Dosing Phase, Day 29  
 Sex: M Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
Continued from previous page ...				
The following tissues are within normal limits both grossly and microscopically:				
Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates
Optic Nerves	Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches
Pharynx	Pituitary Gland	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual
Salivary gland, Submandibular	Seminal Vesicles	Skeletal Muscle	Skull	Spinal Cord, Cervical
Spinal Cord, Lumbar	Spinal Cord, Midthoracic	Spleen	Stemum	Stomach
Testes	Thyroid Gland	Trachea	Urinary Bladder	

Individual Gross and Microscopic Observations				
HSRL		Study: 43166	Printed: 07/24/2017 08:56:36 AM	
		Prisma® Version 6.40 Build 86.HSRL01		
Rat/Sprague-Dawley	Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS	Test Article: Soy Leghemoglobin Preparation	28 Day/Dietary	
Animal #: 7069	Group: 4	Day Of Death: 29	Dosing Phase, Day 29	
	Sex: M	Death Status: Terminal sacrifice		
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
Eyes	No Gross Observations		Rosettes, retina, minimal, focal	
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal	
The following protocol-specified required tissues were not examined microscopically: There are no such tissues				
The following tissues are within normal limits both grossly and microscopically:				
Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Colon	Duodenum	Epithyroides	Esophagus
Femur	Hairerian glands	Heart	Ileum	Jejunum
Kidneys	Larynx	Lungs	Lymph Node, Mandibular	Lymph Node, Mesentere
Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Pancreas	Parathyroid Glands
Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	Pituitary Gland	Prostate Gland
Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	Seminal Vesicles
Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbal	Spinal Cord, Midthoracic
Spleen	Sternum	Stomach	Testes	Thymus
Thyroid Gland	Trachea	Urinary Bladder		

Individual Gross and Microscopic Observations			
HSRL	Study: 43166	Printed: 07/24/2017 08:56:36 AM	
Rat/Sprague-Dawley	Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS	Prisma 7: Version 6.10 Build 86.HSRL01	
Animal #: 7070	Test Article: Soy Leghemoglobin Preparation	Day Of Death: Dosing Phase, Day 29	28 Day: Dietary
	Group: 4		
	Sex: M	Death Status: Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal
Stomach	No Gross Observations		Infiltration, mononuclear cell, minimal, focal
Testes	No Gross Observations		Vacuolation, Sertoli cells, minimal, multifocal
Thymus	No Gross Observations		Increased number, macrophages, tingible body, minimal, diffuse

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Colon	Duodenum	Epididymides	Esoophagus
Eyes	Femur	Hartman glands	Heart	Ileum
Jejunum	Kidneys	Larynx	Lungs	Lymph Node, Mandibular
Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Pancreas
Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	Prostate Gland
Prostate Gland	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular
Seminal Vesicles	Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar

**Individual Gross and Microscopic Observations**

Printed: 07/24/2017 08:56:36 AM  
 Study: 43166  
 PrismaX Version 6.40 Build 86.HSRL01

HSRL  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Test Article: Soy Leghemoglobin Preparation  
 28 Day/Dietary

Rat/Sprague-Dawley  
 Animal #: 7070  
 Group: 4  
 Day Of Death: Dosing Phase, Day 29  
 Sex: M  
 Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscope Observations/Comments
Continued from previous page ...			
The following tissues are within normal limits both grossly and microscopically:			
Spinal Cord, Midthoracic	Spleen	Sperm	Thyroid Gland
Urinary Bladder			Trachea

Individual Gross and Microscopic Observations				Printed: 07/21/2017 08:56:36 AM	
HSRL		Study: 43166		Prismasoft Version 6.4.0 Build 86.HSRL.01	
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS				28 Day: Dietary	
Test Article: Soy Leghemoglobin Preparation					
Rat Sprague-Dawley	Group: 4	Day Of Death:	Dosing Phase, Day 30		
Animal #: 7071	Sex: F	Death Status: Terminal sacrifice			
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments		
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal		
Ovaries	No Gross Observations		Cyst, luteinized, mild, multifocal		
Parathyroid Glands	No Gross Observations		Tissue Comment: Two parathyroids available for evaluation		
Thymus	No Gross Observations		Increased number, macrophages, tingible body, minimal, multifocal		
Vagina	No Gross Observations		Metastasis, present		
The following protocol-specified required tissues were not examined microscopically: There are no such tissues					
The following tissues are within normal limits both grossly and microscopically:					
Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Spleen	Brain	
Cecum	Cervix	Colon	Duodenum	Esophagus	
Eyes	Femur	Harderian glands	Heart	Ileum	
Jejunum	Kidneys	Larynx	Lungs	Lymph Node, Mandibular	
Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Oviducts	
Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	
Pharynx Gland	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	

Individual Gross and Microscopic Observations				
HSRL		Study: 43166		Printed: 07/24/2017 08:56:38 AM
Rat/Sprague-Dawley		Study Title: SOY LEGHEMOGLOBIN PREPARATION. A 28-DAY DIETARY STUDY IN RATS		Pristima® Version 6.40 Build 86.HSRL01
Animal #: 7071	Group: 4	Test Article: Soy Leghemoglobin Preparation	Day Of Death: Dosing Phase, Day 30	28 Day/Dietary
	Sex: F		Death Status: Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
The following tissues are within normal limits both grossly and microscopically:				
Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic
Spleen	Sternum	Stomach	Thyroid Gland	Trachea
Urinary Bladder	Uterus			

Continued from previous page ...

Individual Gross and Microscopic Observations				Printed: 07/24/2017 08:56:36 AM	
HSRL		Study: 43166		Prisma 8 Version 6.4.0 Build 86.HSRL01	
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS					
Test Article: Soy Leghemoglobin Preparation					
Rat Sprague-Dawley	Group: 4	Day Of Death: Dosing Phase, Day 30		28 Day: Dietary	
Animal #: 7072	Sex: F	Death Status: Terminal sacrifice			
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments		
Peyer's Patches	No Gross Observations		Mineralization, mild, multifocal Macrophage aggregates, mild, multifocal		
Pituitary Gland	No Gross Observations		Cystitis, pars distalis, minimal, focal		
Thymus	No Gross Observations		Increased number, macrophages, tangible body, minimal, multifocal		
Vagina	No Gross Observations		Metestrus, present		
The following protocol-specified required tissues were not examined microscopically: There are no such tissues					
The following tissues are within normal limits both grossly and microscopically:					
Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain	
Cecum	Cervix	Colon	Diaphragm	Esophagus	
Eyes	Femur	Harderian glands	Heart	Ileum	
Jejunum	Kidneys	Larynx	Liver	Lungs	
Lymph Node, Mandibular	Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	
Ovaries	Oviducts	Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)	
Pharynx	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	
Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic	

Individual Gross and Microscopic Observations				Printed: 07/24/2017 08:56:36 AM	
HSRL		Study: 43166		Pristima® Version 6.10 Build 86.HSRL01	
Rat Sprague-Dawley		Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS		28 Day/Dietary	
Animal #: 7072		Test Article: Soy Leghemoglobin Preparation		Day Of Death: Dosing Phase, Day 30	
		Group: 4		Death Status: Terminal sacrifice	
		Sex: F			
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments		
Continued from previous page ...					
The following tissues are within normal limits both grossly and microscopically:					
Spleen	Sternum	Stomach	Thyroid Gland	Trachea	
Urinary Bladder	Uterus				



Individual Gross and Microscopic Observations				
HSRL	Study: 43166			Printed: 07/24/2017 08:56:36 AM
	StudyTitle: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS			Pricing: Version 6.40 Build 86 HSRL01
Rat Sprague-Dawley	Test Article: Soy Leghemoglobin Preparation			28 Day Dietary
Animal #: 7073	Group: 4	Day Of Death:	Dosing Phase: Day 28	
	Sex: F	Death Status: Terminal sacrifice		
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
Vagina	No Gross Observations		Metastasis, present	
The following protocol-specified required tissues were not examined microscopically: There are no such tissues				
The following tissues are within normal limits both grossly and microscopically:				
Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Cervix	Colon	Duodenum	Esophagus
Eyes	Femur	Harderian glands	Heart	Hum
Jejunum	Kidneys	Larynx	Liver	Lungs
Lymph Node, Mandibular	Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates	Optic Nerves
Ovaries	Oviducts	Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)
Peyer's Patches	Pharynx	Pituitary Gland	Rectum	Salivary Gland, Parotid
Salivary Gland, Sublingual	Salivary gland, Submandibular	Skeletal Muscle	Skin	Spinal Cord, Cervical
Spinal Cord, Lumbar	Spinal Cord, Midthoracic	Spleen	Sternum	Stomach
Thymus	Thyroid Gland	Trachea	Urinary Bladder	Uterus

Individual Gross and Microscopic Observations				
HSRL	Study: 43166			Printed: 07/24/2017 08:56:36 AM
Rat: Sprague-Dawley	Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS			Pristima® Version 6.4.0 Build 86.HSRL01
Animal #: 7074	Test Article: Soy Leghemoglobin Preparation	Group: 4	Day Of Death: 28 Day/Dietary	28 Day/Dietary
	Sex: F		Day Of Death: 28 Day/Dietary	Death Status: Terminal sacrifice
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
Bone marrow, Femur	No Gross Observations		Decreased myeloid:erythroid ratio, minimal	
Bone Marrow, Sternum	No Gross Observations		Decreased myeloid:erythroid ratio, minimal	
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal	
Vagina	No Gross Observations		Proestrus, present	
The following protocol-specified required tissues were not examined microscopically: There are no such tissues				
The following tissues are within normal limits both grossly and microscopically:				
Adrenal glands	Aorta	Brain	Cecum	Cervix
Colon	Duodenum	Esophagus	Eyes	Femur
Harderian glands	Heart	Ileum	Jejunum	Kidneys
Larynx	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric	Mammary Gland
Nose and Nasal Turbinates	Optic Nerves	Ovaries	Oviducts	Pancreas
Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	Pituitary Gland
Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	Skeletal Muscle
Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic	Spleen

**Individual Gross and Microscopic Observations**

Printed: 07/24/2017 08:56:36 AM  
 Prisma® Version 6.4.0 Build 86.HSRLO1

HSRL  
 Study: 43166  
 StudyTitle: SOY LEGHEMOGLOBIN PREPARATION. A 28-DAY DIETARY STUDY IN RATS  
 Test Article: Soy Leghemoglobin Preparation  
 Day Of Death: Dosing Phase, Day 30  
 28 Day/Dietary

Rat:Sprague-Dawley  
 Animal #: 7074  
 Group: 4  
 Sex: F  
 Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Continued from previous page ...			
The following tissues are within normal limits both grossly and microscopically:			
Spleen	Stomach	Thymus	Thyroid Gland
Urinary Bladder	Uterus		Trachea

Individual Gross and Microscopic Observations				
HSRL	Study: 43166			Printed: 07/24/2017 08:56:36 AM
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS				
Test Article: Soy Leghemoglobin Preparation				
Rat Sprague-Dawley	Group: 4	Day Of Death:	Dosing Phase:	Day 30
Animal #: 7075	Sex: F	Death Status: Terminal sacrifice		
28 Day/Dietary				
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
Liver	No Gross Observations		Infiltrated, mixed cell, minimal, multifocal	
Thymus	No Gross Observations		Increased number, macrophages, tingable body, minimal, diffuse	
Vagina	No Gross Observations		Metestrus, present	
The following protocol-specified required tissues were not examined microscopically: There are no such tissues.				
The following tissues are within normal limits both grossly and microscopically:				
Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sperm	Brain
Cecum	Cervix	Celon	Duodenum	Esophagus
Eyes	Femur	Hardenian glands	Heart	Ileum
Jejunum	Kidneys	Larynx	Lungs	Lymph Node, Mandibular
Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Ovaries
Oviducts	Pancreas	Parathyroid Glands	Peripheral nerve (scatic)	Peyer's Patches
Pharynx	Pituitary Gland	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual
Salivary gland, Submandibular	Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar
Spinal Cord, Midthoracic	Spleen	Sternum	Stomach	Thyroid Gland

**Individual Gross and Microscopic Observations**

Printed: 07/24/2017 08:56:36 AM  
Pridima® Version 6.4.0 Build 86 HSRL01

HSRL Study: 43166  
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day Dietary  
Animal #: 7075 Group: 4 Day Of Death: Dosing Phase, Day 30  
Sex: F Death Status: Terminal sacrifice

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Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
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The following tissues are within normal limits both grossly and microscopically.  
Trachea Urinary Bladder Uterus

Continued from previous page ...

Individual Gross and Microscopic Observations		Printed: 07/24/2017 08:56:36 AM		
HSRL	Study: 43166	Prisma7: Version 6.4.0 Build 86.HSRL01		
Rat: Sprague-Dawley	Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS	Test Article: Soy Leghemoglobin Preparation		
Animal #: 7076	Group: 4	Day Of Death:	Dosing Phase:	Day 30
	Sex: F	Death Status: Terminal sacrifice		
Tissue	Gross Observations/Comments	Status	Microscope Observations/Comments	
Kidneys	No Gross Observations		Infiltration, mononuclear cell, interstitial, minimal, focal	
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal	
Thymus	No Gross Observations		Increased number, macrophages, tingible body, minimal, diffuse	
Vagina	No Gross Observations		Proestrus, present	
The following protocol-specified required tissues were not examined microscopically: There are no such tissues				
The following tissues are within normal limits both grossly and microscopically:				
Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Cervix	Cecum	Diaphragm	Esophagus
Eyes	Femur	Harderian glands	Heart	Ileum
Jejunum	Larynx	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric
Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Ovaries	Oviducts
Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx
Pituitary Gland	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular
Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic

**Individual Gross and Microscopic Observations**

Printed: 07/24/2017 08:56:39 AM  
Pristima® Version 6.4.0 Build 86 HSRL01

HSRL Study: 43166  
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
Animal #: 7076 Group: 4 Day Of Death: Dosing Phase, Day 30  
Sex: F Death Status: Terminal sacrifice

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Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
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Continued from previous page ...

The following tissues are within normal limits both grossly and microscopically:

Spleen	Sternum	Stomach	Thyroid Gland	Trachea
Urinary Bladder	Uterus			

Individual Gross and Microscopic Observations				
HSRL	Study: J3166			Printed: 07/24/2017 08:50:30 AM
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS		Prisma® Version 6.4.0 Build 86.HSRL01		
Rat Sprague-Dawley	Test Article: Soy Leghemoglobin Preparation			28 Day/Dietary
Animal #: 7077	Group: 4	Day Of Death:	Dosing Phase, Day 30	
	Sex: F	Death Status: Terminal sacrifice		
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
Kidneys	No Gross Observations		Infiltration, mononuclear cell, interstitial, minimal, focal	
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal	
Thymus	No Gross Observations		Increased number, macrophages, tingible body, minimal, diffuse	
Vagina	No Gross Observations		Metestrus, present	
The following protocol-specified required tissues were not examined microscopically: There are no such tissues				
The following tissues are within normal limits both grossly and microscopically:				
Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Cervix	Colon	Duodenum	Esophagus
Eyes	Femur	Hankerson glands	Heart	Heum
Jejunum	Larynx	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric
Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Ovaries	Oviducts
Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx
Pituitary Gland	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular
Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Thoracic



Individual Gross and Microscopic Observations			
HSRL	Study: 43166	Printed: 07/24/2017 08:56:36 AM	
	Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS	Prism: Version 6.10 Build 86.HSRL01	
Rat Sprague-Dawley	Test Article: Soy Leghemoglobin Preparation	28 Day: Dietary	
Animal #: 7077	Group: 4	Day Of Death: Dosing Phase, Day 30	
	Sex: F	Death Status: Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
			Continued from previous page ...
The following tissues are within normal limits both grossly and microscopically.			
Spleen	Sernan	Stomach	Thyroid Gland Trachea
Urinary Bladder	Uterus		

Individual Gross and Microscopic Observations				Printed: 07/24/2017 08:56:36 AM	
HSRL		Study: 43166		Pristima® Version 6.4.0 Build 86 HSRL01	
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS					
Lab/Sprague-Dawley		Test Article: Soy Leghemoglobin Preparation		28 Day/Dietary	
Animal #: 7078		Group: 4		Day Of Death: Dosing Phase, Day 30	
		Sex: F		Death Status: Terminal sacrifice	
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments		
Larynx	No Gross Observations		Infiltration, neutrophil, minimal, focal		
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal		
Salivary Gland, Parotid	No Gross Observations		One of the pair is Missing Within Normal Limits		
Thymus	No Gross Observations		Increased number, macrophages, tingible body, minimal, diffuse		
Vagina	No Gross Observations		Metastasis, present		
The following protocol-specified required tissues were not examined microscopically: There are no such tissues					
The following tissues are within normal limits both grossly and microscopically:					
Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain	
Cecum	Cervix	Colon	Duodenum	Esophagus	
Eyes	Femur	Harderian glands	Heart	Hemum	
Jejunum	Kidneys	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric	
Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Ovaries	Oviducts	
Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx	
Pituitary Gland	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular	

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:56:38 AM  
 Study: 43166 Prism: 2, Version 6.4.0 Build 86, HSRL01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat/Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day: Dietary  
 Animal #: 7078 Group: 4 Day Of Death: Dosing Phase, Day 30  
 Sex: F Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
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Continued from previous page ...

The following tissues are within normal limits both grossly and microscopically:

Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic
Spleen	Sternum	Stomach	Thyroid Gland	Trachea
Urinary Bladder	Uterus			

Individual Gross and Microscopic Observations				Printed: 07/24/2017 08:56:36 AM
HSRL	Study: 43166		Pristima® Version 6.1.0 Build 86.HSRL01	
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS				
Test Article: Soy Leghemoglobin Preparation				
Rat: Sprague-Dawley	Group: 4	Day Of Death:	Dosing Phase, Day 30	28 Day/Dietary
Animal #: 7079	Sex: F	Death Status: Terminal sacrifice		
Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments	
Urinary Bladder	No Gross Observations		Tissue Comment: The epithelium appears vacuolated but this change may be a stretch artifact caused at necropsy. Vacuolation, epithelium, mild, locally extensive	
Vagina	No Gross Observations		Metestus, present	
The following protocol-specified required tissues were not examined microscopically: There are no such tissues				
The following tissues are within normal limits both grossly and microscopically:				
Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Cervix	Colon	Diaphragm	Esophagus
Eyes	Femur	Hardenian glands	Heart	Jejunum
Jejunum	Kidneys	Larynx	Liver	Lungs
Lymph Node, Mandibular	Lymph Node, Mesenteric	Mammary Gland	Nose and Nasal Turbinates	Optic Nerves
Ovaries	Oviducts	Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)
Peyer's Patches	Pharynx	Pituitary Gland	Rectum	Salivary Gland, Parotid
Salivary Gland, Sublingual	Salivary gland, Submandibular	Skeletal Muscle	Skin	Spinal Cord, Cervical
Spinal Cord, Lumbar	Spinal Cord, Midthoracic	Spleen	Sternum	Stomach
Thymus	Thyroid Gland	Trachea	Uterus	

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/24/2017 08:56:36 AM  
 Study: 43166 Prisma® Version 6.4.0 Build 86.HSRL01  
 Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
 Rat Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
 Animal #: 7080 Group: 4 Day Of Death: Dosing Phase, Day 30  
 Sex: F Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Kidneys	No Gross Observations		Infiltration, mononuclear cell, interstitial, minimal, focal Basophilic, tubules, minimal, multifocal
Liver	No Gross Observations		Infiltration, mixed cell, minimal, multifocal
Vagina	No Gross Observations		Metestrus, present

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues

The following tissues are within normal limits both grossly and microscopically:

Adrenal glands	Aorta	Bone marrow, Femur	Bone Marrow, Sternum	Brain
Cecum	Cervix	Colon	Diaphragm	Esophagus
Eyes	Femur	Harderian glands	Heart	Intestine
Jejunum	Larynx	Lungs	Lymph Node, Mandibular	Lymph Node, Mesenteric
Mammary Gland	Nose and Nasal Turbinates	Optic Nerves	Ovaries	Oviducts
Pancreas	Parathyroid Glands	Peripheral nerve (sciatic)	Peyer's Patches	Pharynx
Pituitary Gland	Rectum	Salivary Gland, Parotid	Salivary Gland, Sublingual	Salivary gland, Submandibular
Skeletal Muscle	Skin	Spinal Cord, Cervical	Spinal Cord, Lumbar	Spinal Cord, Midthoracic
Spleen	Sternum	Stomach	Thymus	Thyroid Gland

**Individual Gross and Microscopic Observations**

HSRL Printed: 07/21/2017 08:56:36 AM  
Study: 43166 Pristima® Version 6.4.0 Build 86.HSRL01  
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
Rat/Sprague-Dawley Test Article: Soy Leghemoglobin Preparation 28 Day/Dietary  
Animal #: 7080 Group: 4 Day Of Death: Dosing Phase, Day 30  
Sex: F Death Status: Terminal sacrifice

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Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
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The following tissues are within normal limits both grossly and microscopically:  
Trachea                      Urinary Bladder                      Uterus

Continued from previous page ...

**Individual Gross and Microscopic Observations**

Printed: 07/24/2017 08:55:50 AM  
Pristima® Version 6.4.0 Build 86.HSRL.01

HSRL  
Study: 43166  
Study Title: SOY LEGHEMOGLOBIN PREPARATION: A 28-DAY DIETARY STUDY IN RATS  
Test Article: Soy Leghemoglobin Preparation  
28 Day: Dietary

Rat Sprague-Dawley  
Animal #: 7060  
Group: 3  
Sex: F  
Day Of Death: Dosing Phase, Day 30  
Death Status: Terminal sacrifice

Tissue	Gross Observations/Comments	Status	Microscopic Observations/Comments
Vagina	No Gross Observations		Tissue Comment: Only cervix and scant vagina present. Metestrus, present

The following protocol-specified required tissues were not examined microscopically:  
There are no such tissues.

The following tissues are within normal limits both grossly and microscopically:  
Cervix                      Ovaries                      Oviducts                      Uterus

Final Pathology Report  
Impossible Foods, Inc.  
PSL Study Number 43166

**Appendix B. Quality Assurance Statement**



**HSRL** HistoScientific Research Laboratories

**QUALITY ASSURANCE STATEMENT**

Study Title: Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats

Client Study Number: 43166

This histopathology project has been inspected and audited by the HSRL Quality Assurance Unit (QAU) as required by the Good Laboratory Practice (GLP) regulations disseminated by the U.S. Food and Drug Administration (FDA, 21 CFR 58).

<u>Area Inspected</u>	<u>Inspection</u> <sup>1</sup>	<u>Dates</u>	
		<u>Reported</u> <sup>2</sup>	<u>Reported</u> <sup>3</sup>
Critical Phase: Quality Control	16NOV16	17NOV16	17NOV16
Data Review	18NOV16	23NOV16	23NOV16
Data Review	16DEC16	19DEC16	19DEC16
Pathology Report: Draft	20-21DEC16	22DEC16	22DEC16
Final	20JUL17	24JUL17	24JUL17

All the results/conclusions of the pathology report accurately reflect the raw data.

<sup>1</sup> Date(s) of inspection

<sup>2</sup> Date(s) inspections reported to HSRL Laboratory Director/Test Site Management, Principal Investigator/HSRL Study Pathologist

<sup>3</sup> Date(s) inspections reported to Study Director, Test Facility Management, and Lead QA (if appropriate)

(b) (6)

Victoria L. Cook, RQAP-GLP  
Director of Quality Assurance

24 Jul 17

Date

## **APPENDIX U: HISTOPATHOLOGY PEER REVIEW**

### **PRODUCT IDENTIFICATION**

Soy Leghemoglobin Preparation

#### **Submitted By:**

Regan Path/Tox Services, Inc,  
1457 Township Road 853  
Ashland, OH 44805

Regan Path/Tox Services, Inc.

**PATHOLOGY PEER REVIEW STATEMENT**

**Soy Leghemoglobin Preparation: A 28-Day Dietary Study in Rats**

**Testing Facility Study No.: Product Safety Labs 43166**

**Methods:**

A pathology peer review for study Product Safety Labs 43166 was conducted by a board certified veterinary pathologist between the dates of June 13, 2017 and June 26, 2017. The review consisted of the following:

- 1) Examination of all slides of ovaries, uterus, cervix and vagina from all females on study
- 2) Review of macroscopic and microscopic pathology data and the narrative pathology report

**Results:**

The pathology data and pathology report reflect the consensus opinions of the study pathologist and peer review pathologist. The signed final pathology report was reviewed by the undersigned reviewing pathologist prior to completion of this peer review statement.

(b) (6)

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Karen S. Regan, DVM, DACVP, DABT  
Peer Review Pathologist  
Regan Path/Tox Services, Inc.

\_\_\_\_\_  
Date

July 25 2017