

Table 1

## Clinical Sign - Summary

B131138

## Day numbers relative to Start Date

Group	Sex	Clinical Sign	1	1	2	3	4	5	6	7	8	8	9	10	11	12	13	14	15	15	16	17	18		
			BD	T10	am	am	am	am	am	am	am	BD	T10	am	am	am	am	am	am	BD	T10	am	am	am	
1	m	ANIMALS ALIVE	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	
		ANIMALS NORMAL	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
2	m	ANIMALS ALIVE	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
		ANIMALS NORMAL	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
3	m	ANIMALS ALIVE	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	5	5	4	
		ANIMALS NORMAL	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	5	5	4	
4	m	Death	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	1	.	1	
		Abnormal gait	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
		Anemic	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
		ANIMALS ALIVE	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	5	5	4	4	4
4	m	ANIMALS NORMAL	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	5	5	4	4	4	
		Death	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	1	.	1	.	.	

Group 1 - 0 mg/kg    Group 2 - 1 mg/kg    Group 3 - 10 mg/kg    Group 4 - 25 mg/kg

Table 1

## Clinical Sign - Summary

B131138

Group	Sex	Clinical Sign	Day numbers relative to Start Date												
			19 am	20 am	21 am	22 BD	22 T10	23 am	24 am	25 am	26 am	27 am	28 am	29 am	29 pm
1	m	ANIMALS ALIVE	6	6	6	6	6	6	6	6	6	6	6	6	.
		ANIMALS NORMAL	6	6	6	6	6	6	6	6	6	6	6	6	.
2	m	ANIMALS ALIVE	6	6	6	6	6	6	6	6	6	6	6	6	.
		ANIMALS NORMAL	6	6	6	6	6	6	6	6	6	6	6	6	.
3	m	ANIMALS ALIVE	3	3	3	3	3	3	3	3	3	3	3	3	.
		ANIMALS NORMAL	3	3	3	3	3	3	3	3	3	3	2	2	.
4	m	Death	1	.	.	.	.	.	.	.	.	.	.	.	.
		Abnormal gait	.	.	.	.	.	.	.	.	.	.	1	1	.
		Anemic	.	.	.	.	.	.	.	.	.	.	.	1	.
4	m	ANIMALS ALIVE	4	4	4	4	4	4	4	4	4	4	3	3	.
		ANIMALS NORMAL	4	4	4	4	4	4	4	4	4	4	3	3	.
		Death	.	.	.	.	.	.	.	.	.	.	1	.	1

Group 1 - 0 mg/kg    Group 2 - 1 mg/kg    Group 3 - 10 mg/kg    Group 4 - 25 mg/kg

Table 1

## Clinical Sign - Summary

B131138

Day numbers relative to Start Date

Group	Sex	Clinical Sign	1	1	2	3	4	5	6	7	8	8	9	10	11	12	13	14	15	15	16	17	18		
			BD	T10	am	am	am	am	am	am	am	BD	T10	am	am	am	am	am	BD	T10	am	am	am		
1	f	ANIMALS ALIVE	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	
		ANIMALS NORMAL	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
2	f	ANIMALS ALIVE	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
		ANIMALS NORMAL	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
3	f	ANIMALS ALIVE	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
		ANIMALS NORMAL	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
4	f	ANIMALS ALIVE	6	6	6	6	6	6	6	6	6	6	6	6	6	6	5	5	4	3	3	3	3	3	3
		ANIMALS NORMAL	6	6	6	6	6	6	6	6	6	6	6	6	6	6	5	4	4	3	3	3	3	3	3
		Death	.	.	.	.	.	.	.	.	.	.	.	.	.	.	1	.	1	1	.	.	.	.	
		Anemic	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	1	.	.	.	.	.	.	

Group 1 - 0 mg/kg    Group 2 - 1 mg/kg    Group 3 - 10 mg/kg    Group 4 - 25 mg/kg

Table 1

## Clinical Sign - Summary

B131138

Day numbers relative to Start Date

Group	Sex	Clinical Sign	19 am	20 am	21 am	22 BD	22 T10	23 am	24 am	25 am	26 am	27 am	28 am	29 am
1	f	ANIMALS ALIVE	6	6	6	6	6	6	6	6	6	6	6	6
		ANIMALS NORMAL	6	6	6	6	6	6	6	6	6	6	6	6
2	f	ANIMALS ALIVE	6	6	6	6	6	6	6	6	6	6	6	6
		ANIMALS NORMAL	6	6	6	6	6	6	6	6	6	6	6	6
3	f	ANIMALS ALIVE	6	6	6	6	6	6	6	6	6	6	6	6
		ANIMALS NORMAL	6	6	6	6	6	6	6	6	6	6	6	6
4	f	ANIMALS ALIVE	1	1	1	1	1	0	0	0	0	0	0	0
		ANIMALS NORMAL	1	1	1	1	1	0	.	.	.	.	.	.
		Death Anemic	2	.	.	.	.	1	.	.	.	.	.	.

Group 1 - 0 mg/kg    Group 2 - 1 mg/kg    Group 3 - 10 mg/kg    Group 4 - 25 mg/kg

Table 2 Body Weight - Summary

B131138

Bodyweight (g)

Sex: Male		Day(s) Relative to Start Date				
		1	8	15	22	28
0 mg/kg	Mean	344.00 I <sup>1</sup>	376.00 I <sup>1</sup>	407.27 I <sup>1</sup>	433.58 I <sup>1</sup>	433.25 I <sup>1</sup>
	SD	13.09	25.70	29.02	30.13	39.63
	N	6	6	6	6	6
1 mg/kg	Mean	345.30	367.05	395.65	425.18	431.10
	SD	14.17	27.53	32.92	32.23	33.42
	N	6	6	6	6	6
10 mg/kg	Mean	347.85	371.72	383.93	434.20	413.23
	SD	14.15	26.10	42.76	39.47	41.61
	N	6	6	6	3	3
25 mg/kg	Mean	343.13	372.88	387.92	424.05	400.13
	SD	13.36	12.33	25.13	9.04	24.78
	N	6	6	5	4	3

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

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1 [I - Automatic Transformation: Identity]

Table 2 Body Weight - Summary

B131138

Bodyweight (g)

Sex: Female		Day(s) Relative to Start Date				
		1	8	15	22	28
0 mg/kg	Mean	237.28 <sup>1</sup>	249.97 <sup>1</sup>	257.28 <sup>1</sup>	267.10 <sup>1</sup>	271.07 <sup>1</sup>
	SD	10.95	14.11	12.11	14.28	14.55
	N	6	6	6	6	6
1 mg/kg	Mean	231.60	245.83	254.35	264.43	264.22
	SD	14.90	9.70	8.90	11.27	11.96
	N	6	6	6	6	6
10 mg/kg	Mean	237.50	246.30	257.03	266.17	267.27
	SD	13.19	18.49	19.38	23.50	16.99
	N	6	6	6	6	6
25 mg/kg	Mean	236.03	252.67	262.18	287.40 <sup>n1<sup>2</sup></sup>	-
	SD	12.03	18.23	27.08	-	-
	N	6	6	4	1	-

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

1 [I - Automatic Transformation: Identity]

2 [n1 - This group has only one value]

Table 3 Food Consumption - Summary

B131138

Food Mean Daily Consumption (g/day)

Sex: Male		Day(s) Relative to Start Date			
		1 → 8	8 → 15	15 → 22	22 → 27
0 mg/kg	Mean	27.97 <sup>1</sup>	27.21 <sup>1</sup>	28.13 <sup>1</sup>	28.32 <sup>1</sup>
	SD	1.55	1.57	1.42	1.49
	N	6	6	6	6
1 mg/kg	Mean	27.02	25.67	27.30	27.90
	SD	2.90	2.12	1.69	2.17
	N	6	6	6	6
10 mg/kg	Mean	26.98	24.08	26.50	20.70 <sup>d2</sup>
	SD	2.07	3.51	2.55	2.15
	N	6	6	3	3
25 mg/kg	Mean	28.03	24.58	27.34	20.23 <sup>dd3</sup>
	SD	2.26	3.91	2.33	7.08
	N	6	5	4	4

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

1 [I - Automatic Transformation: Identity]  
 3 [dd - Test: Dunnett 2 Sided p < 0.01]

2 [d - Test: Dunnett 2 Sided p < 0.05]

Table 3 Food Consumption - Summary

B131138

Food Mean Daily Consumption (g/day)

Sex: Female		Day(s) Relative to Start Date			
		1 → 8	8 → 15	15 → 22	22 → 27
0 mg/kg	Mean	19.83 <sup>1</sup>	20.29 <sup>1</sup>	21.16 <sup>1</sup>	20.15 <sup>1</sup>
	SD	1.16	1.63	1.89	1.84
	N	6	6	6	6
1 mg/kg	Mean	19.98	19.67	20.27	18.00
	SD	1.54	1.56	1.79	1.80
	N	6	6	6	6
10 mg/kg	Mean	19.68	19.94	20.26	19.24
	SD	1.91	1.70	1.64	1.85
	N	6	6	6	6
25 mg/kg	Mean	19.21	19.28	21.19 n1 <sup>2</sup>	.
	SD	2.31	2.82	.	.
	N	6	4	1	.

Statistical Test: Generalised Anova/Ancova Test Transformation: Automatic

1 [I - Automatic Transformation: Identity]

2 [n1 - This group has only one value]



Table 4

Ophthalmologic Examination - Summary

B131138

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Day numbers relative to Start Date

Group	Sex	Clinical Sign	-2	26
1	m	ANIMALS ALIVE	6	6
		ANIMALS NORMAL	5	5
		Corneal opacity	.	1
		Particulate opacity in lens	1	1
2	m	ANIMALS ALIVE	6	6
		ANIMALS NORMAL	3	3
		Corneal opacity	1	2
		Particulate opacity in lens	3	3
		Focal opacity in lens	1	1
3	m	ANIMALS ALIVE	6	3
		ANIMALS NORMAL	6	3
4	m	ANIMALS ALIVE	6	4
		ANIMALS NORMAL	3	2
		Corneal opacity	1	1
		Particulate opacity in lens	1	1
		Persistent hyaloid artery	1	.

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Group 1 - 0 mg/kg    Group 2 - 1 mg/kg    Group 3 - 10 mg/kg    Group 4 - 25 mg/kg

Table 4

Ophthalmologic Examination - Summary

B131138

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Day numbers relative to Start Date

Group	Sex	Clinical Sign	-5	26
1	f	ANIMALS ALIVE	6	6
		ANIMALS NORMAL	5	5
		Particulate opacity in lens	1	1
2	f	ANIMALS ALIVE	6	6
		ANIMALS NORMAL	5	5
		Focal opacity in lens	1	1
3	f	ANIMALS ALIVE	6	6
		ANIMALS NORMAL	2	3
		Corneal opacity	3	2
		Focal opacity in lens	1	1
4	f	ANIMALS ALIVE	6	0
		ANIMALS NORMAL	5	.
		Particulate opacity in lens	1	.

Group 1 - 0 mg/kg

Group 2 - 1 mg/kg

Group 3 - 10 mg/kg

Group 4 - 25 mg/kg

Table 5-1 Urinalysis - Summary

B131138

Day: 27 Relative to Start Date

Sex: Male		pH										Protein	
		Sampled	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	>=9.0	-	+/-
0 mg/kg	N+ve	.	0	0	0	0	0	0	1	5	0	3	3
	Total	6	.	.	.	.	.	.	.	.	.	.	.
1 mg/kg	N+ve	.	0	0	0	0	0	0	0	6	0	0	6
	Total	6	.	.	.	.	.	.	.	.	.	.	.
10 mg/kg	N+ve	.	0	0	0	0	0	0	0	3	0	1	1
	Total	3	.	.	.	.	.	.	.	.	.	.	.
25 mg/kg	N+ve	.	0	0	0	0	0	0	2	2	0	1	3
	Total	4	.	.	.	.	.	.	.	.	.	.	.

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Table 5-1 Urinalysis - Summary

B131138

Day: 27 Relative to Start Date

Sex: Male		Protein			Glucose					Ketone			
		1+	2+	3+	-	1+	2+	3+	4+	-	+/-	1+	2+
0 mg/kg	N+ve	0	0	0	6	0	0	0	0	0	2	4	0
	Total	.	.	.	.	.	.	.	.	.	.	.	.
1 mg/kg	N+ve	0	0	0	6	0	0	0	0	0	1	5	0
	Total	.	.	.	.	.	.	.	.	.	.	.	.
10 mg/kg	N+ve	1	0	0	3	0	0	0	0	1	0	2	0
	Total	.	.	.	.	.	.	.	.	.	.	.	.
25 mg/kg	N+ve	0	0	0	4	0	0	0	0	0	3	1	0
	Total	.	.	.	.	.	.	.	.	.	.	.	.

Table 5-1 Urinalysis - Summary

B131138

Day: 27 Relative to Start Date

Sex: Male		Ketone	Bilirubin					Occult Blood					Crystal	
			3+	-	1+	2+	3+	-	+/-	1+	2+	3+	-	1+
0 mg/kg	N+ve	0	6	0	0	0	4	2	0	0	0	4	2	
	Total	.	.	.	.	.	.	.	.	.	.	.	.	
1 mg/kg	N+ve	0	6	0	0	0	5	0	1	0	0	3	3	
	Total	.	.	.	.	.	.	.	.	.	.	.	.	
10 mg/kg	N+ve	0	3	0	0	0	3	0	0	0	0	2	1	
	Total	.	.	.	.	.	.	.	.	.	.	.	.	
25 mg/kg	N+ve	0	3	1	0	0	3	0	0	0	1	3	1	
	Total	.	.	.	.	.	.	.	.	.	.	.	.	

Table 5-1 Urinalysis - Summary

B131138

Day: 27 Relative to Start Date

Sex: Male		Crystal		Red Blood Cell				White Blood Cell				Epithelial Cell	
		2+	3+	-	1+	2+	3+	-	1+	2+	3+	-	1+
0 mg/kg	N+ve	0	0	5	1	0	0	5	1	0	0	3	3
	Total	.	.	.	.	.	.	.	.	.	.	.	.
1 mg/kg	N+ve	0	0	5	1	0	0	3	3	0	0	4	2
	Total	.	.	.	.	.	.	.	.	.	.	.	.
10 mg/kg	N+ve	0	0	3	0	0	0	3	0	0	0	1	2
	Total	.	.	.	.	.	.	.	.	.	.	.	.
25 mg/kg	N+ve	0	0	3	0	1	0	3	0	1	0	1	3
	Total	.	.	.	.	.	.	.	.	.	.	.	.

Table 5-1 Urinalysis - Summary

B131138

Day: 27 Relative to Start Date

Sex: Male		Epithelial Cell		Cast			
		2+	3+	-	1+	2+	3+
0 mg/kg	N+ve	0	0	6	0	0	0
	Total	.	.	.	.	.	.
1 mg/kg	N+ve	0	0	6	0	0	0
	Total	.	.	.	.	.	.
10 mg/kg	N+ve	0	0	3	0	0	0
	Total	.	.	.	.	.	.
25 mg/kg	N+ve	0	0	4	0	0	0
	Total	.	.	.	.	.	.

Table 5-1 Urinalysis - Summary

B131138

Day: 27 Relative to Start Date

Sex: Female		pH										Protein	
		Sampled	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	>=9.0	-	+/-
0 mg/kg	N+ve	.	0	0	0	1	0	0	1	4	0	3	1
	Total	6	.	.	.	.	.	.	.	.	.	.	.
1 mg/kg	N+ve	.	0	0	0	0	0	0	0	6	0	2	3
	Total	6	.	.	.	.	.	.	.	.	.	.	.
10 mg/kg	N+ve	.	0	0	0	1	0	2	0	3	0	0	5
	Total	6	.	.	.	.	.	.	.	.	.	.	.



Table 5-1 Urinalysis - Summary

B131138

Day: 27 Relative to Start Date

Sex: Female		Protein			Glucose					Ketone			
		1+	2+	3+	-	1+	2+	3+	4+	-	+/-	1+	2+
0 mg/kg	N+ve	1	1	0	6	0	0	0	0	0	5	1	0
	Total	.	.	.	.	.	.	.	.	.	.	.	.
1 mg/kg	N+ve	1	0	0	6	0	0	0	0	1	3	2	0
	Total	.	.	.	.	.	.	.	.	.	.	.	.
10 mg/kg	N+ve	1	0	0	6	0	0	0	0	0	2	4	0
	Total	.	.	.	.	.	.	.	.	.	.	.	.

Table 5-1 Urinalysis - Summary

B131138

Day: 27 Relative to Start Date

Sex: Female		Ketone	Bilirubin				Occult Blood					Crystal	
			3+	-	1+	2+	3+	-	+/-	1+	2+	3+	-
0 mg/kg	N+ve	0	6	0	0	0	6	0	0	0	0	2	4
	Total	.	.	.	.	.	.	.	.	.	.	.	.
1 mg/kg	N+ve	0	6	0	0	0	6	0	0	0	0	5	1
	Total	.	.	.	.	.	.	.	.	.	.	.	.
10 mg/kg	N+ve	0	6	0	0	0	6	0	0	0	0	4	2
	Total	.	.	.	.	.	.	.	.	.	.	.	.

Table 5-1 Urinalysis - Summary

B131138

Day: 27 Relative to Start Date

Sex: Female		Crystal		Red Blood Cell				White Blood Cell				Epithelial Cell	
		2+	3+	-	1+	2+	3+	-	1+	2+	3+	-	1+
0 mg/kg	N+ve	0	0	6	0	0	0	5	1	0	0	4	2
	Total	.	.	.	.	.	.	.	.	.	.	.	.
1 mg/kg	N+ve	0	0	6	0	0	0	6	0	0	0	5	0
	Total	.	.	.	.	.	.	.	.	.	.	.	.
10 mg/kg	N+ve	0	0	6	0	0	0	5	1	0	0	6	0
	Total	.	.	.	.	.	.	.	.	.	.	.	.

Table 5-1 Urinalysis - Summary

B131138

Day: 27 Relative to Start Date

Sex: Female		Epithelial Cell		Cast			
		2+	3+	-	1+	2+	3+
0 mg/kg	N+ve	0	0	6	0	0	0
	Total	.	.	.	.	.	.
1 mg/kg	N+ve	1	0	6	0	0	0
	Total	.	.	.	.	.	.
10 mg/kg	N+ve	0	0	6	0	0	0
	Total	.	.	.	.	.	.