

Table 18

Study No. B041794

Body Weight Gain (P0 Gestation) - Summary
 Base : Day 0 of Gestation

Test Substance Dose (mg/kg)	/Day	Unit : g			
		0	7	14	20
CCH 0	Mean	0.0	41.8	79.0	161.0
	S.D.	0.0	10.5	16.6	23.5
	n	12	12	12	12
CCH 10	Mean	0.0	39.4	73.7	148.4
	S.D.	0.0	7.4	11.9	21.6
	n	12	12	12	12
CCH 60	Mean	0.0	42.9	82.7	165.1
	S.D.	0.0	7.0	11.5	23.7
	n	12	12	12	12
CCH 300	Mean	0.0	35.3	70.1	145.7
	S.D.	0.0	7.4	11.7	17.8
	n	12	12	12	12

Significantly different from control

: *, P<0.05; **, P<0.01.

Table 19

Study No. B041794

Body Weight Gain (FO Lactation) - Summary
 Base : Day 0 of Lactation

Unit : g

Test Substance Dose (mg/kg)	/Day		
	0	0	4
CCH 0	Mean	0.0	19.6
	S.D.	0.0	9.6
	n	12	12
CCH 10	Mean	0.0	8.4*
	S.D.	0.0	8.2
	n	11	11
CCH 60	Mean	0.0	7.8**
	S.D.	0.0	8.5
	n	12	11
CCH 300	Mean	0.0	13.6
	S.D.	0.0	9.9
	n	12	12

Significantly different from control

: *, P<0.05; **, P<0.01.

Female #

Table 20 Accumulative Body Weight Gain - Summary

Test Substance Dose (mg/kg)	Accumulative Body Weight Gain - Summary									
	Day	22	29	36	42	43	50	56	Female #	
CCH 0	Mean	0.0	5.6	15.4	32.0	31.4	40.0	45.4		
	S.D.	0.0	3.0	12.2	12.6	12.4	12.7	18.2		
	n	5	5	5	5	5	5	5		
CCH 300	Mean	0.0	7.4	18.4	29.2	30.2	45.2	59.6		
	S.D.	0.0	5.0	6.5	5.8	7.2	12.3	12.8		
	n	5	5	5	5	5	5	5		

Significantly different from control : *, P<0.05; **, P<0.01.

#: Satellite animal

Table 21 Food Consumption - Summary

Test Substance Dose (mg/kg)	Day	Male									
		8	15	22	29	36	38	50	52		
CCH 0	Mean	24.23	21.68	22.22	22.22	22.63	21.79	26.92	26.00		
	S.D.	2.20	1.50	1.22	1.22	1.22	1.89	1.33	1.22		
	n	12	12	11	12	12	12	5	5		
CCH 10	Mean	24.05	22.47	23.29	23.29	23.46	22.67				
	S.D.	2.21	2.18	2.21	2.21	2.46	1.91				
	n	12	12	10	12	12	12				
CCH 60	Mean	23.55	21.68	22.40	23.23	23.23	23.29				
	S.D.	2.08	2.36	2.01	2.00	2.66	2.66				
	n	12	12	11	12	12	12				
CCH 300	Mean	23.17	22.02	22.43	23.23	23.23	23.08	28.90	29.10		
	S.D.	2.28	2.09	1.76	2.10	2.41	3.62	3.71	3.71		
	n	12	12	12	12	12	5	5	5		

Significantly different from control : *, P<0.05; **, P<0.01.

Female

Table 22 Food Consumption - Summary

Test Substance Dose (mg/kg)	Day			Mean	S.D.	n
	8	15	17			
CCH 0	17.41	16.43	17	1.30	2.02	17
	17.19	16.53	12	2.23	2.58	12
	16.63	15.67	12	1.17	1.55	12
CCH 10	16.49	15.56	17	1.35	0.82	17
	17.19	16.53	12	2.23	2.58	12
	16.63	15.67	12	1.17	1.55	12
CCH 60	16.49	15.56	17	1.35	0.82	17
	17.19	16.53	12	2.23	2.58	12
	16.63	15.67	12	1.17	1.55	12
CCH 300	16.49	15.56	17	1.35	0.82	17
	17.19	16.53	12	2.23	2.58	12
	16.63	15.67	12	1.17	1.55	12

Significantly different from control : *.P<0.05; **.P<0.01.

Table 23

Food Consumption (F0 Gestation) - Summary

Test Substance Dose (mg/kg)	/Day			14	20
	7	14	20		
CCH 0	Mean	19.3	20.4	21.7	
	S.D.	2.2	2.3	2.1	
	n	12	12	12	
CCH 10	Mean	20.0	21.1	21.6	
	S.D.	2.2	2.0	2.0	
	n	12	12	12	
CCH 60	Mean	19.8	21.9	22.8	
	S.D.	1.6	2.0	1.9	
	n	12	12	12	
CCH 300	Mean	18.3	20.4	21.6	
	S.D.	2.2	2.0	2.1	
	n	12	12	12	

Significantly different from control

: *P<0.05; **P<0.01.

Table 24

Study No. B041794

Food Consumption (F0 Lactation) - Summary

Test Substance Dose (µg/kg)	/Day		4
	Mean S.D. n	Mean S.D. n	
CCH 0	33.5 3.9 12	29.3 3.3 11	4
CCH 10	30.5 4.4 11	30.3 4.2 12	
CCH 60			
CCH 300			

Significantly different from control : *, P<0.05; **, P<0.01.

Table 25

Test Substance Dose (mg/kg)	Day	Female #					
		22	29	36	42	50	56
0	Mean	17.02	16.20	16.96	16.46	20.36	20.28
	S.D.	1.85	1.61	2.00	1.81	2.15	1.76
	n	5	5	5	5	5	5
300	Mean	15.68	16.40	17.68	16.88	22.46	22.80
	S.D.	1.53	0.93	1.19	1.39	1.57	1.70
	n	5	5	5	5	5	5

Significantly different from control : *, P<0.05; **, P<0.01.

‡: Satellite animal

Male

Table 25 Hematology - Summary

Test Substance Dose (mg/kg)	Red Blood Cell Count x10 ⁶ /μL	Hemoglobin		Hematocrit		MCV		MCH		MCHC		Platelet Count x10 ³ /μL		Reticulocyte Ratio %		PT sec	
		Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57
CCH 0	Mean	8.298	15.58	45.48	45.36	54.80	58.12	18.74	18.00	34.24	33.94	1055.6	970.4	2.58	2.64	24.30	22.98
	S.D. n	0.118 5	0.27 5	0.84 5	1.19 5	1.34 5	2.54 5	0.45 5	0.52 5	0.22 5	0.72 5	163.6 5	73.1 5	0.13 5	0.11 5	5.16 5	3.39 5
CCH 10	Mean	8.618	15.46	45.88	53.26	17.94	17.94	33.68	33.68	972.0	972.0	2.40	2.40	21.90	21.90	1.90	1.90
	S.D. n	0.203 5	0.51 5	1.14 5	0.84 5	0.39 5	0.39 5	0.60 5	0.60 5	131.7 5	131.7 5	0.57 5	0.57 5	1.90 5	1.90 5	1.90 5	1.90 5
CCH 60	Mean	8.318	15.32	44.95	54.06	18.44	18.44	34.10	34.10	974.8	974.8	2.48	2.48	25.16	25.16	4.83	4.83
	S.D. n	0.219 5	0.31 5	1.36 5	0.36 5	0.18 5	0.18 5	0.45 5	0.45 5	93.4 5	93.4 5	0.29 5	0.29 5	4.83 5	4.83 5	4.83 5	4.83 5
CCH 300	Mean	8.512	15.42	45.40	53.44	18.14	18.14	33.94	33.94	985.8	985.8	3.26*	3.26*	20.72	20.72	2.30*	2.30*
	S.D. n	0.487 5	0.54 5	1.80 5	2.24 5	1.37 5	1.82 5	0.84 5	0.44 5	0.38 5	0.57 5	104.4 5	89.6 5	0.35 5	0.23 5	2.30 5	3.94 5

Significantly different from control : *P<0.05; **P<0.01.

Table 26 Hematology - Summary

Test Substance Dose (mg/kg)	APTT sec	Day 43		Day 57	
		Mean	S.D.	Mean	S.D.
0	Mean	22.88	20.98		
	S.D.	2.35	1.58		
10	Mean	21.46			
	S.D.	1.79			
60	Mean	23.78			
	S.D.	3.17			
300	Mean	20.24	21.48		
	S.D.	1.67	2.75		

Significantly different from control : *P<0.05; **P<0.01.

Table 26 Hematology - Summary

Test Substance Dose (mg/kg)	White Blood Cell Count x10E3/ μ L	Day 43		Day 57	
		Mean	S.D.	Mean	S.D.
CCH 0	Mean	8.868	7.792		
	S.D.	2.381	0.868		
	n	5	5		
CCH 10	Mean	9.406			
	S.D.	1.529			
	n	5			
CCH 60	Mean	9.968			
	S.D.	1.451			
	n	5			
CCH 300	Mean	9.668	7.636		
	S.D.	1.353	0.731		
	n	5	5		

Significantly different from control : *, P<0.05; **, P<0.01.

Table 26 Hematology - Summary

Male

Test Substance Dose (mg/kg)	Lymphocyte %		Neutrophilic Segmented %		Neutrophilic Band %		Eosinophil %		Basophil %		Monocyte %	
	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57
CCH 0	Mean	85.94	8.04	10.24	0.00	0.00	1.00	0.60	0.00	0.00	1.80	3.22
	S.D.	2.77	4.83	4.97	4.97	0.00	0.00	0.71	0.89	0.00	1.64	1.96
	n	5	5	5	5	5	5	5	5	5	5	5
CCH 10	Mean	83.40	13.60	0.40	0.00	0.60	0.60	0.00	0.00	0.00	2.00	
	S.D.	2.41	1.14	0.55	0.55	0.55	0.55	0.00	0.00	0.00	1.58	
	n	5	5	5	5	5	5	5	5	5	5	
CCH 60	Mean	85.96	11.84	0.00	0.00	1.00	1.00	0.00	0.00	0.00	1.20	
	S.D.	3.58	3.18	0.00	0.00	1.22	1.22	0.00	0.00	0.00	0.84	
	n	5	5	5	5	5	5	5	5	5	5	
CCH 300	Mean	87.50	10.30	11.24	0.00	0.00	1.40	0.20	0.00	0.00	0.80	3.00
	S.D.	4.34	5.46	5.04	4.77	0.00	0.00	0.55	0.45	0.00	0.45	1.00
	n	5	5	5	5	5	5	5	5	5	5	5

Significantly different from control : *, P<0.05; **, P<0.01.

Female

Table 27 Hematology - Summary

Test Substance Dose (mg/kg)	Red Blood Cell Count x10 ⁶ /μL		Hemoglobin conc. g/dL		Hematocrit %		MCV fL		MCH pg		MCHC %		Platelet Count x10 ³ /μL		Reticulocyte Ratio %		PT sec	
	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57
CCH 0	Mean	6.850	8.370	13.16	15.30	39.24	44.12	57.38	19.30	18.30	33.64	34.70	1078.2	1049.8	6.10	2.36	17.72	15.18
	S.D.	0.453	0.333	0.43	0.42	1.54	0.97	2.79	0.87	0.69	0.30	0.37	140.2	132.4	1.87	0.36	0.76	0.64
	n	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
CCH 10	Mean	6.790		13.16		38.52		56.72	19.36		34.12		1172.8		6.08		17.48	
	S.D.	0.158		0.34		1.09		0.63	0.25		0.28		151.5		1.32		1.16	
	n	5		5		5		5	5		5		5		5		5	
CCH 60	Mean	6.758		13.16		38.98		57.74	19.46		33.72		1132.4		6.58		18.18	
	S.D.	0.215		0.51		0.94		2.25	0.82		0.64		168.0		1.73		0.70	
	n	5		5		5		5	5		5		5		5		5	
CCH 300	Mean	6.926	7.964	13.56	15.26	39.74	43.92	57.44	19.60	19.16	34.12	34.76	1162.2	985.8	6.00	2.40	18.38	16.24
	S.D.	0.564	0.259	0.81	0.55	3.08	1.78	1.95	0.65	0.57	0.64	0.19	184.6	162.7	1.54	0.65	0.66	0.85
	n	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5

Significantly different from control : *P<0.05; **P<0.01.

Table 27 Hematology - Summary

Test Substance Dose (mg/kg)	APTT sec	Day 43		Day 57	
		Mean	S.D.	Mean	S.D.
CCH 0		16.18	1.14	15.22	1.77
		n	n	n	n
		5	5	5	5
CCH 10		15.60	1.00		
		n	n		
		5	5		
CCH 60		15.90	0.83		
		n	n		
		5	5		
CCH 300		15.52	0.73	15.08	0.97
		n	n	n	n
		5	5	5	5

Significantly different from control : * P<0.05; ** P<0.01.

Table 27 Hematology - Summary

Test Substance Dose (mg/kg)	White Blood Cell Count x10 ⁹ /μL	Day 43		Day 57	
		Mean	S.D.	Mean	S.D.
CCH 0		8.410	2.005	5.700	0.681
		n	n	n	n
		5	5	5	5
CCH 10		9.860	0.608		
		n	n		
		5	5		
CCH 60		9.698	2.926		
		n	n		
		5	5		
CCH 300		9.136	0.713	7.276	2.319
		n	n	n	n
		5	5	5	5

Significantly different from control : *P<0.05; **P<0.01.

Table 27 Hematology - Summary

Test Substance Dose (mg/kg)	Female													
	Lymphocyte %				Neutrophilic Segmented %		Neutrophilic Band %		Eosinophil %		Basophil %		Monocyte %	
	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57
CCH 0	Mean	73.66	90.58	23.32	8.02	0.20	0.00	0.20	0.60	0.00	0.00	0.00	2.62	0.80
	S.D.	5.54	5.66	5.55	5.03	0.45	0.00	0.45	0.89	0.00	0.00	0.00	2.18	0.84
	n	5	5	5	5	5	5	5	5	5	5	5	5	5
CCH 10	Mean	70.54	26.26	0.60	0.40	0.00	0.00	0.40	0.00	0.00	0.00	2.20		
	S.D.	4.24	4.18	0.89	0.89	0.00	0.00	0.89	0.00	0.00	0.00	1.79		
	n	5	5	5	5	5	5	5	5	5	5	5		
CCH 60	Mean	65.90	31.30	0.20	0.40	0.00	0.00	0.40	0.00	0.00	0.00	2.20		
	S.D.	11.59	11.23	0.45	0.55	0.00	0.00	0.55	0.45	0.00	0.00	1.79		
	n	5	5	5	5	5	5	5	5	5	5	5		
CCH 300	Mean	76.80	91.58	19.80	6.62	0.60	0.00	0.20	0.20	0.00	0.00	0.00	2.60	1.60
	S.D.	7.85	4.83	7.40	4.45	0.89	0.00	0.45	0.45	0.00	0.00	0.00	2.07	0.89
	n	5	5	5	5	5	5	5	5	5	5	5	5	5

Significantly different from control : *, P<0.05; **, P<0.01.

Male

Table 28 Blood Chemistry - Summary

Test Substance Dose (mg/kg)	ASAT (GOT) U/L		ALAT (GPT) U/L		γGT U/L		ALP U/L		Total Bilirubin mg/dL		Urea Nitrogen mg/dL		Creatinine mg/dL		Glucose mg/dL		Total Cholesterol mg/dL		
	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	
CCH	Mean	98.0	114.4	28.2	28.8	0.4	1.4	406.8	318.0	0.10	0.08	12.18	13.72	0.30	0.30	131.8	125.8	56.2	64.6
	S.D.	22.3	21.5	3.1	4.5	0.5	0.5	144.7	51.9	0.00	0.04	1.38	1.48	0.00	0.07	7.8	8.8	14.4	9.6
	n	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
CCH	Mean	99.6		32.2		1.0		365.6		0.10		13.62		0.30		146.2		64.8	
	S.D.	22.4		12.3		0.7		70.0		0.00		1.73		0.07		17.7		13.5	
	n	5		5		5		5		5		5		5		5		5	
CCH	Mean	88.4		26.0		0.6		384.8		0.08		12.18		0.28		145.0		62.2	
	S.D.	15.6		5.4		0.5		69.2		0.04		1.76		0.08		11.0		12.9	
	n	5		5		5		5		5		5		5		5		5	
CCH	Mean	96.6	109.6	29.8	29.4	1.0	1.6	414.4	287.6	0.10	0.05	11.74	14.06	0.26	0.24	124.4	130.4	65.6	74.2
	S.D.	19.8	16.6	8.6	4.6	0.7	0.5	52.8	50.5	0.00	0.05	1.32	1.06	0.05	0.05	15.0	11.2	6.7	21.3
	n	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5

Significantly different from control : *, P<0.05; **, P<0.01.

Male

Table 28 Blood Chemistry - Summary

Test Substance Dose (mg/kg)	Triglyceride mg/dL		Total Protein g/dL		Albumin g/dL		A/G Ratio		Calcium mg/dL		Inorganic Phosphorus mg/dL		Na mmol/L		K mmol/L		Cl mmol/L		
	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	
CCH 0	Mean	30.2	29.0	6.52	6.70	3.04	3.02	0.848	0.826	9.94	9.82	8.20	7.96	148.2	149.0	4.80	4.46	105.2	105.2
	S.D.	15.4	9.5	0.24	0.14	0.11	0.11	0.019	0.078	0.23	0.19	0.36	0.83	1.1	0.7	0.23	0.19	1.2	0.8
	n	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
CCH 10	Mean	49.6		6.80		3.08		0.832		10.12		7.72		148.0		4.68		105.2	
	S.D.	32.8		0.32		0.13		0.036		0.28		0.72		0.0		0.26		0.8	
	n	5		5		5		5		5		5		5		5		5	
CCH 60	Mean	37.8		6.70		3.06		0.844		10.02		7.94		148.8		4.54		105.2	
	S.D.	10.2		0.37		0.05		0.079		0.37		0.68		0.8		0.21		0.8	
	n	5		5		5		5		5		5		5		5		5	
CCH 300	Mean	24.6	40.6	6.70	6.72	3.08	3.08	0.856	0.836	9.98	10.06	8.74	7.66	148.6	148.8	4.72	4.64	105.2	105.2
	S.D.	8.4	13.6	0.12	0.23	0.04	0.08	0.027	0.034	0.36	0.34	0.55	0.48	0.9	0.8	0.11	0.23	1.3	1.3
	n	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5

Significantly different from control : * P<0.05; ** P<0.01.

Table 29 Blood Chemistry - Summary

Female

Test Substance Dose (mg/kg)	ASAT (GOT) U/L		ALAT (GPT) U/L		γGT U/L		ALP U/L		Total Bilirubin mg/dL		Urea Nitrogen mg/dL		Creatinine mg/dL		Glucose mg/dL		Total Cholesterol mg/dL	
	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57
CCH	Mean 0	142.4 27.2 5	53.8 10.1 5	22.0 4.2 5	1.0 0.0 5	2.2 0.4 5	356.0 178.0 5	144.0 48.8 5	0.08 0.04 5	0.10 0.00 5	19.18 2.42 5	14.18 2.31 5	0.36 0.05 5	0.32 0.04 5	135.8 9.9 5	137.8 9.9 5	65.2 13.3 5	82.8 25.8 5
CCH	Mean 10	116.0 20.5 5	38.6 6.6 5	238.0 48.3 5	1.4 0.9 5	2.2 0.4 5	298.0 48.3 5	144.0 48.8 5	0.06 0.05 5	0.10 0.00 5	20.42 5.48 5	14.18 2.31 5	0.38 0.08 5	0.32 0.04 5	124.2 7.7 5	137.8 9.9 5	66.8 16.8 5	82.8 25.8 5
CCH	Mean 60	142.8 23.0 5	46.0 6.6 5	239.4 60.2 5	0.6 0.5 5	2.2 0.4 5	298.0 48.3 5	144.0 48.8 5	0.06 0.05 5	0.10 0.00 5	18.00 2.14 5	14.18 2.31 5	0.40 0.00 5	0.32 0.04 5	124.8 8.8 5	137.8 9.9 5	65.2 12.8 5	82.8 25.8 5
CCH	Mean 300	139.2 26.2 5	50.0 9.3 5	293.0 107.7 5	1.0 1.0 5	1.4* 0.5 5	293.0 107.7 5	165.4 31.0 5	0.05 0.05 5	0.10 0.00 5	22.16 2.51 5	15.74 2.27 5	0.32 0.08 5	0.32 0.04 5	134.4 10.1 5	126.4 12.4 5	67.2 11.3 5	83.2 15.3 5

Significantly different from control : *P<0.05; **P<0.01.

Female

Table 29 Blood Chemistry - Summary

Test Substance Dose (mg/kg)	Triglyceride mg/dL		Total Protein g/dL		Albumin g/dL		A/G Ratio		Calcium mg/dL		Inorganic Phosphorus mg/dL		Na mmol/L		K mmol/L		Cl mmol/L	
	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57
CCH 0	Mean	17.2	6.78	7.24	3.02	0.932	11.38	10.32	0.818	0.932	10.38	7.74	146.4	147.2	4.84	4.64	102.0	106.0
	S.D.	30.5	0.41	0.56	0.18	0.34	0.51	0.36	0.048	0.055	0.89	0.52	0.9	1.3	0.39	0.21	1.6	2.4
	n	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
CCH 10	Mean	57.4	6.28	2.94	0.890	10.94	10.16	0.890	0.890	10.16	10.16	4.52	146.4	147.2	4.52	4.52	105.0	105.0
	S.D.	27.0	0.50	0.29	0.086	0.51	0.49	0.49	0.086	0.49	0.49	0.16	0.5	0.5	0.16	0.16	2.6	2.6
	n	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
CCH 60	Mean	39.4	6.74	3.12	0.862	11.14	10.20	0.862	0.862	11.14	10.20	4.76	146.8	147.0	4.76	4.76	103.4	103.4
	S.D.	16.9	0.17	0.26	0.086	0.40	1.01	0.8	0.086	0.40	1.01	0.25	0.8	0.8	0.25	0.25	3.0	3.0
	n	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
CCH 300	Mean	59.6	16.2	7.16	0.880	10.82	8.66*	0.880	0.880	10.82	8.35	8.35	147.0	147.0	4.48	4.78	105.4	105.6
	S.D.	49.5	5.0	0.22	0.074	0.29	0.28	0.28	0.074	0.28	0.85	0.57	1.4	1.9	0.25	0.24	1.9	2.2
	n	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5

Significantly different from control : *P<0.05; **P<0.01.

Male

Table 30 Urinalysis - Summary

Test Substance Dose (mg/kg)	pH	Protein	Glucose	Ketones	Bilirubin	Occult Blood
0	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >9	- +/- 1+ 2+ 3+	- +/- 1+ 2+ 3+	- +/- 1+ 2+ 3+	- 1+ 2+ 3+	- +/- 1+ 2+ 3+
	Day 38	Day 38	Day 38	Day 38	Day 38	Day 38
CCH	0	0 0 0 0 0 1 2 2	0 0 0 0 0 0 0 0	0 0 3 2 0	5 0 0 0	5 0 0 0
CCH	10	0 0 0 0 0 0 1 4	0 0 0 0 0 5 0 0	0 1 3 1 0	5 0 0 0	5 0 0 0
CCH	60	0 0 0 0 0 0 1 4	0 0 0 0 0 4 1 0	0 0 3 2 0	5 0 0 0	5 0 0 0
CCH	300	0 0 0 0 0 0 1 3 1	0 0 0 0 0 5 0 0	0 1 3 1 0	5 0 0 0	5 0 0 0

Significantly different from control : *P<0.05; **P<0.01.

Male

Table 80 Urinalysis - Summary

Test Substance Dose (mg/kg)	Urobilinogen BU/dl 0.1 1.0 2.0 4.0 >=8 Day 38
CCH 0 n	4 1 0 0 0
CCH 10 n	4 1 0 0 0
CCH 60 n	2 3 0 0 0
CCH 300 n	4 1 0 0 0

Significantly different from control : *P<0.05; **P<0.01.

Table 31 Organ Weight - Summary

Male

Test Substance Dose (mg/kg)	Final Body Weight		Brain		Thymus		Heart		Liver		Spleen		Kidneys		Adrenals		Testes		
	g	g	g	g	mg	g	g	g	g	g	g	g	g	g	mg	mg	g	g	
	Day 43	Day 57	Day 43	Day 43	Day 43	Day 43	Day 43	Day 43	Day 43	Day 43	Day 43	Day 43	Day 43	Day 43	Day 43	Day 43	Day 43	Day 43	Day 43
CCH 0	Mean	483.7	500.0	2.144	2.142	335.6	360.8	1.562	1.596	12.074	12.786	0.804	0.834	3.004	3.334	60.56	55.62	3.497	3.434
	S.D.	36.4	21.0	0.054	0.076	65.2	81.9	0.123	0.109	1.622	0.747	0.099	0.139	0.214	0.199	9.72	5.16	0.349	0.141
	n	7	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	7	5
CCH 10	Mean	489.0		2.112		280.0		1.642		12.992		0.800		2.816		69.98		3.359	
	S.D.	34.5		0.051		92.9		0.123		2.151		0.137		0.128		8.04		0.332	
	n	12		5		5		5		5		5		5		5		12	
CCH 60	Mean	479.8		2.150		327.2		1.490		12.836		0.876		3.184		65.40		3.361	
	S.D.	43.9		0.143		21.6		0.127		1.974		0.149		0.273		6.18		0.555	
	n	12		5		5		5		5		5		5		5		12	
CCH 300	Mean	436.6	499.6	2.072	2.102	300.6	335.6	1.562	1.724	12.318	14.326	0.806	0.806	3.326	3.756	56.46	53.56	3.493	3.246
	S.D.	24.5	43.5	0.051	0.067	50.8	67.7	0.165	0.185	1.288	1.793	0.098	0.075	0.279	0.555	3.85	7.00	0.221	0.745
	n	7	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	7	5

Significantly different from control : *, P<0.05; **, P<0.01.

Table 31 Organ Weight - Summary

Test Substance Dose (mg/kg)	Epididymides		g	
	Day 43	Day 57	Mean	S.D.
CCH 0	Mean	1.299	1.350	
	S.D.	0.112	0.091	
CCH 10	Mean	1.258		
	S.D.	0.146		
CCH 60	Mean	1.291		
	S.D.	0.176		
CCH 300	Mean	1.299	1.292	
	S.D.	0.109	0.274	

Significantly different from control : *, P<0.05; **, P<0.01.

Table 32

Organ Weight -- Summary (F0 Delivered-on Weaning)

Sex : Female

Test Substance Dose (mg/kg)	Mean S.D. n	F. B. W. (g)	Brain (g)	Thymus (mg)	Heart (g)	Liver (g)	Spleen (g)	Kidneys (g)	Adrenals (mg)
CCH 0	Mean	305.8	1.966	214.2	1.084	10.886	0.708	2.072	70.24
	S.D.	27.0	0.069	71.3	0.047	0.786	0.086	0.148	10.73
	n	5	5	5	5	5	5	5	5
CCH 10	Mean	295.4	1.884	253.8	1.036	10.494	0.750	1.854	74.22
	S.D.	24.5	0.042	23.0	0.099	1.544	0.109	0.115	7.94
	n	5	5	5	5	5	5	5	5
CCH 60	Mean	299.0	1.922	232.6	1.032	10.664	0.808	1.968	76.22
	S.D.	12.8	0.036	76.2	0.077	0.932	0.271	0.186	5.97
	n	5	5	5	5	5	5	5	5
CCH 300	Mean	286.0	1.884	228.6	0.942*	10.890	0.658	2.006	66.24
	S.D.	17.4	0.070	67.9	0.057	0.576	0.092	0.134	6.76
	n	5	5	5	5	5	5	5	5

Significantly different from control

: *P<0.05; **P<0.01.

Female #

Organ Weight - Summary

Test Substance Dose (mg/kg)	Final Body Weight g	Brain g	Thymus mg	Heart g	Liver g	Spleen g	Kidneys g	Adrenals mg
CCH 0	Mean	1.952	273.2	0.968	7.484	0.468	1.828	66.85
	S.D.	0.030	38.6	0.057	0.565	0.094	0.206	12.71
	n	5	5	5	5	5	5	5
CCH 300	Mean	1.910	304.6	0.924	7.812	0.596*	1.886	69.92
	S.D.	0.029	36.7	0.059	0.573	0.076	0.119	12.29
	n	5	5	5	5	5	5	5

Significantly different from control : *P<0.05; **P<0.01.
#.Satellite animal

Table 34 Relative Organ Weight - Summary

Test Substance Dose (mg/kg)	Final Body Weight (g)		Brain %		Thymus x10 ⁻³ %		Heart %		Liver %		Spleen %		Kidneys %		Adrenals x10 ⁻³ %		Testes %	
	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57	Day 43	Day 57
CCH 0	Mean	483.7	500.0	0.428	69.92	72.42	0.326	0.340	2.516	2.558	0.168	0.166	0.628	0.668	12.56	11.32	0.726	0.588
	S.D.	36.4	21.0	0.038	9.47	16.78	0.018	0.034	0.144	0.049	0.029	0.021	0.049	0.040	0.98	0.83	0.082	0.028
	n	7	5	5	5	5	5	5	5	5	5	5	5	5	5	5	7	5
CCH 10	Mean	489.0	448	0.448	58.40	0.346	0.346	2.732	2.732	0.168	0.168	0.596	0.596	12.72	12.72	0.692	0.692	
	S.D.	34.5	0.028	15.54	0.023	0.023	0.023	0.317	0.317	0.031	0.031	0.040	0.040	1.93	1.93	0.092	0.092	
	n	12	5	5	5	5	5	5	5	5	5	5	5	5	5	12	12	
CCH 60	Mean	479.8	0.460	70.24	0.318	2.726	2.726	0.188	0.188	0.188	0.188	0.678	0.678	14.06	14.06	0.705	0.705	
	S.D.	43.9	0.016	9.06	0.015	0.015	0.215	0.215	0.041	0.041	0.041	0.066	0.066	2.02	2.02	0.124	0.124	
	n	12	5	5	5	5	5	5	5	5	5	5	5	5	5	12	12	
CCH 300	Mean	486.6	0.474	68.36	0.382	2.308	2.308	0.344	2.860**	0.186	0.160	0.762**	0.750**	12.92	10.68	0.803	0.650	
	S.D.	24.5	0.034	8.76	0.032	0.032	0.196	0.009	0.131	0.027	0.007	0.067	0.052	1.00	0.66	0.052	0.142	
	n	7	5	5	5	5	5	5	5	5	5	5	5	5	5	7	5	

Significantly different from control : *, P<0.05; **, P<0.01.

Table 34 Relative Organ Weight - Summary

Test Substance Dose (mg/kg)	Epididymides %	Day 43		Day 57			
		Mean	S.D.	n	Mean	S.D.	n
CCH 0		0.270	0.037	7	0.270	0.012	5
CCH 10		0.259	0.039	12			
CCH 60		0.270	0.038	12			
CCH 300		0.257	0.021	7	0.258	0.054	5

Significantly different from control : *, P<0.05; **, P<0.01.

Table 35

Study No. B041794

Relative Organ Weight - Summary (F0 Delivered-on Weaning)

Sex : Female

Unit : g/100gBW

Test Substance Dose (mg/kg)	Mean S.D. n	F.B.W. (g)	Brain	Thymus (x10 ⁻⁵)	Heart	Liver	Spleen	Kidneys	Adrenals (x10 ⁻³)
CCH 0	305.8 27.0 5	0.646 0.048 5	68.98 18.05 5	0.356 0.027 5	3.568 0.295 5	0.232 0.028 5	0.680 0.062 5	23.04 3.48 5	
CCH 10	295.4 24.5 5	0.642 0.053 5	86.40 10.77 5	0.348 0.015 5	3.536 0.288 5	0.254 0.026 5	0.628 0.020 5	25.14 1.74 5	
CCH 60	299.0 12.8 5	0.642 0.023 5	77.26 22.89 5	0.346 0.021 5	3.562 0.213 5	0.268 0.080 5	0.658 0.038 5	25.48 1.65 5	
CCH 300	286.0 17.4 5	0.662 0.053 5	79.60 19.25 5	0.330 0.020 5	3.818 0.245 5	0.230 0.025 5	0.702 0.050 5	23.22 2.43 5	

Significantly different from control : *, P<0.05; **, P<0.01.

Female #

Table 36 Relative Organ Weight - Summary

Test Substance Dose (mg/kg)	Final Body Weight g	Brain		Thymus		Heart		Liver		Spleen		Kidneys		Adrenals	
		%	Day 57	x10 ⁻³ %	Day 57	%	Day 57	%	Day 57	%	Day 57	%	Day 57	x10 ⁻³ %	Day 57
CCH 0	Mean	289.8	0.678	93.94	0.332	2.584	0.150	0.628	23.02	0.628	0.024	0.041	3.80	5	
	S.D. n	19.5 5	0.048 5	8.69 5	0.016 5	0.095 5	0.024 5	0.041 5	3.80 5	0.024 5	0.024 5	0.041 5	3.80 5	5	
CCH 300	Mean	282.2	0.676	108.20	0.330	2.766*	0.212*	0.666	24.74	0.666	0.025	0.019	3.98	5	
	S.D. n	11.8 5	0.030 5	14.53 5	0.010 5	0.120 5	0.025 5	0.019 5	3.98 5	0.025 5	0.025 5	0.019 5	3.98 5	5	

Significantly different from control : *P<0.05; **P<0.01.

#:Satellite animal

Table 37 Necropsy Findings - Summary

Organ Findings	Sex	Test Substance	Male		Female	
			CCH mg/kg	CCH mg/kg	CCH mg/kg	CCH mg/kg
Dose	0	0	0	0	0	0
Dose Unit			300	300	60	60
Number of Animals	7	7	7	7	12	12
Number of Animals Examined	<7>	<7>	<12>	<12>	<11>	<11>
Thymus Small		0	0	0	0	0
Liver Abnormal lobation		0	0	0	1	0
Nodule		2	0	0	0	0
Testis Small		0	0	1	0	0
Soft		0	0	1	0	0
Epididymis Small		0	0	1	0	0
Yellowish change		0	0	1	0	0

Table 37 Necropsy Findings - Summary

Organ Findings	Sex	Male		Female	
		Test Substance	CCH	CCH	CCH
Dose		10	0	10	60
Dose Unit		mg/kg	mg/kg	mg/kg	mg/kg
Number of Animals		12	7	12	12
Number of Animals Examined		<0>	<0>	<0>	<1>
Thymus					
Small				0	1
Spleen					
Small				0	1
Ovary					
Cystic dilatation				1	0
Uterus					
Fetal rest				1	0

Table 37 Necropsy Findings - Summary

Organ Findings	Sex		Scheduled Sacrifice (Recovery)	
	Male	Female	CCH	CCH
Test Substance	CCH	CCH	300	300
Dose	0	0	mg/kg	mg/kg
Dose Unit	mg/kg	mg/kg	5	5
Number of Animals	5	5	<5>	<5>
Number of Animals Examined	<5>	<5>		
Testis	0		1	
Small				

Table 38 Histological Findings - Summary

Organ Findings	Sex	Test Substance	Scheduled Sacrifice			
			Male	Female	Male	Female
			CCH	CCH	CCH	CCH
		Dose	mg/kg	mg/kg	mg/kg	mg/kg
		Number of Animals	7	7	12	12
			Grade			
Heart Cell infiltration, inflammatory			<5>	<0>	<0>	<5>
			3	2	2	2
			0	0	0	0
			0	0	0	0
Lymph node, mandibular			<5>	<0>	<0>	<5>
			3	3	3	3
			0	0	0	0
			0	0	0	0
Lymph node, mesenteric			<5>	<0>	<0>	<5>
			3	3	3	3
			0	0	0	0
			0	0	0	0
Thymus Atrophy			<5>	<0>	<0>	<5>
			1	0	0	3
			2	0	0	0
			3	0	0	0
Spleen Extramedullary hematopoiesis, erythrocytic			<5>	<0>	<0>	<5>
			1	0	0	3
			2	0	0	0
			3	0	0	0
Bone marrow, femur			<5>	<0>	<0>	<5>
			1	0	0	4
			2	0	0	0
			3	0	0	0

◇, Number of animals examined
1, Minimal; 2, Mild; 3, Moderate; 4, Severe

Table 38 Histological Findings - Summary

Scheduled Sacrifice

Organ Findings	Sex	Test Substance	Dose Unit	Number of Animals	Grade	Male				Female				
						CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH	
						mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	
Trachea Dilatation, tracheal gland	1	<5>	<0>	<0>	<5>	<0>	<0>	<0>	<5>	<0>	<0>	<5>	<0>	<0>
	2	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0
Lung (and bronchus) Accumulation, foam cell, alveolus	1	<5>	<0>	<0>	<5>	<0>	<0>	<0>	<5>	<0>	<0>	<5>	<0>	<0>
	2	1	0	0	2	0	0	0	2	0	0	2	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0
Hemorrhage	1	1	0	0	0	0	0	0	1	0	0	0	0	0
	2	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0
Metaplasia, osseous	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0
Mineralization, arterial wall	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0

◇, Number of animals examined
 1, Minimal; 2, Mild; 3, Moderate; 4, Severe

Table 38 Histological Findings - Summary

Scheduled Sacrifice

Organ Findings	Sex	Test Substance	Dose	Dose Unit	Number of Animals	Male				Female				
						CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH	
						mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	
Stomach					Grade	<5>	<0>	<0>	<0>	<5>	<0>	<0>	<0>	<5>
Ectopic pancreatic tissue					1	0	<0>	<0>	<0>	1	<0>	<0>	<0>	0
					2	0	<0>	<0>	<0>	0	<0>	<0>	<0>	0
					3	0	<0>	<0>	<0>	0	<0>	<0>	<0>	0
					4	0	<0>	<0>	<0>	0	<0>	<0>	<0>	0
Small intestine, duodenum					<5>	<0>	<0>	<0>	<0>	<5>	<0>	<0>	<0>	<5>
Small intestine, jejunum					<5>	<0>	<0>	<0>	<0>	<5>	<0>	<0>	<0>	<5>
Small intestine, ileum					<5>	<0>	<0>	<0>	<0>	<5>	<0>	<0>	<0>	<5>
Large intestine, cecum					<5>	<0>	<0>	<0>	<0>	<5>	<0>	<0>	<0>	<5>
Large intestine, colon					<5>	<0>	<0>	<0>	<0>	<5>	<0>	<0>	<0>	<5>
Large intestine, rectum					<5>	<0>	<0>	<0>	<0>	<5>	<0>	<0>	<0>	<5>
Liver					<5>	<0>	<0>	<0>	<0>	<5>	<0>	<0>	<0>	<5>
Cell infiltration, inflammatory, focal					1	2	<0>	<0>	<0>	2	<0>	<0>	<0>	1
					2	0	<0>	<0>	<0>	0	<0>	<0>	<0>	0
					3	0	<0>	<0>	<0>	0	<0>	<0>	<0>	0
					4	0	<0>	<0>	<0>	0	<0>	<0>	<0>	0
Patty change, hepatocyte, focal					1	2	0	0	0	0	0	0	0	0
					2	0	0	0	0	0	0	0	0	0
					3	0	0	0	0	0	0	0	0	0
					4	0	0	0	0	0	0	0	0	0

◇, Number of animals examined
 1, Minimal; 2, Mild; 3, Moderate; 4, Severe

Table 38 Histological Findings - Summary

Scheduled Sacrifice

Organ Findings	Sex	Test Substance	Dose	Dose Unit	Number of Animals	Grade	Male				Female				
							CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH	
							mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg
Liver Vacuolation, hepatocyte, perilobular							<5>	<0>	<0>	<4>	<6>	<0>	<0>	<5>	<0>
						1	2	10	60	300	0	10	60	300	0
						2	0	12	12	7	0	12	12	12	0
						3	0	0	0	0	0	0	0	0	0
Kidney Basophilic tubule, proximal tubule							<5>	<5>	<5>	<5>	<5>	<0>	<0>	<5>	<0>
						1	4	1	2	1	3	10	60	1	10
						2	0	0	0	0	0	12	12	0	12
						3	0	0	0	0	0	0	0	0	0
Cast, hyaline, tubule							0	0	1	0	0	0	0	0	0
						1	1	0	0	0	0	0	0	0	0
						2	0	0	0	0	0	0	0	0	0
						3	0	0	0	0	0	0	0	0	0
Cell infiltration, lymphocyte, interstitium							0	0	0	0	0	0	0	0	0
						1	1	2	0	2	1	10	60	0	10
						2	0	0	0	0	0	0	0	0	0
						3	0	0	0	0	0	0	0	0	0
Hyaline droplet, proximal tubular epithelium							0	0	0	0	0	0	0	0	0
						1	0	1	1	0	0	1	1	0	0
						2	0	0	0	0	0	0	0	0	0
						3	0	0	0	0	0	0	0	0	0

◇, Number of animals examined
 1, Minimal; 2, Mild; 3, Moderate; 4, Severe
 Significantly different from control : **, P<0.01.

Table 38 Histological Findings - Summary

Scheduled Sacrifice

Organ Findings	Sex	Test Substance Dose	Dose Unit	Number of Animals	Grade	Male		Female		CCH mg/kg	CCH mg/kg	CCH mg/kg	CCH mg/kg
						CCH mg/kg	7	CCH mg/kg	12				
Urinary bladder						<5>	<5>	<5>	<5>	<5>	<5>	<5>	<5>
Cell infiltration, lymphocyte, lamina propria					1	0	0	0	0	0	0	0	1
					2	0	0	0	0	0	0	0	0
					3	0	0	0	0	0	0	0	0
					4	0	0	0	0	0	0	0	0
Hyperplasia, mucosal epithelium					1	0	0	2	2	4	0	0	4 *
					2	0	0	0	0	0	0	0	0
					3	0	0	0	0	0	0	0	0
					4	0	0	0	0	0	0	0	0
Testis						<5>	<5>	<1>	<5>	<5>	<5>	<5>	<5>
Atrophy, seminiferous tubular epithelium					1	1	0	0	0	0	0	0	0
					2	0	0	1	0	0	0	0	0
					3	0	0	0	0	0	0	0	0
					4	0	0	0	0	0	0	0	0
Epididymis						<5>	<5>	<2>	<5>	<5>	<5>	<5>	<5>
Cell debris, duct					1	0	0	1	0	0	0	0	0
					2	0	0	0	0	0	0	0	0
					3	0	0	0	0	0	0	0	0
					4	0	0	0	0	0	0	0	0
Cell infiltration, lymphocyte, focal					1	0	0	0	0	1	0	0	0
					2	0	0	0	0	0	0	0	0
					3	0	0	0	0	0	0	0	0
					4	0	0	0	0	0	0	0	0

◇, Number of animals examined
 1, Minimal; 2, Mild; 3, Moderate; 4, Severe
 Significantly different from control ; *, P<0.05.

Table 38 Histological Findings - Summary

Organ Findings	Sex	Test Substance Dose	Scheduled Sacrifice									
			Male			Female						
			CCH mg/kg	Number of Animals	Grade	CCH mg/kg	Number of Animals	Grade				
Epididymis Decrease, sperm, duct			<5>	<0>	<2>	<5>	<0>	<0>	<5>	<0>	<0>	<5>
			0	1	0	0	0	0	0	0	0	0
			0	0	1	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0
Granulomatous inflammation, spermatic			0	1	1	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	0
Seminal vesicle			<5>	<0>	<0>	<5>	<0>	<0>	<5>	<0>	<0>	<5>
			<5>	<0>	<0>	<5>	<0>	<0>	<5>	<0>	<0>	<5>
Prostate Cell infiltration, lymphocyte, interstitium			2	0	0	3	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
Coagulating gland			<5>	<0>	<0>	<5>	<0>	<0>	<5>	<0>	<0>	<5>
			<5>	<0>	<0>	<5>	<0>	<0>	<5>	<0>	<0>	<5>
Ovary			<5>	<0>	<0>	<5>	<0>	<0>	<5>	<0>	<0>	<5>
Uterus			<5>	<0>	<0>	<5>	<0>	<0>	<5>	<0>	<0>	<5>
Vagina			<5>	<0>	<0>	<5>	<0>	<0>	<5>	<0>	<0>	<5>

◇, Number of animals examined
 1, Minimal; 2, Mild; 3, Moderate; 4, Severe

Table 38 Histological Findings - Summary

Organ Findings	Sex	Test Substance	Dose	Dose Unit	Number of Animals	Scheduled Sacrifice									
						Male					Female				
						CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH
					Grade	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg
Pituitary						<5>	<0>	<0>	<5>	<5>	<0>	<0>	<0>	<5>	<5>
Aberrant craniopharyngeal tissue, posterior lobe					1	0	0	0	0	0	0	0	0	1	0
					2	0	0	0	0	0	0	0	0	0	0
					3	0	0	0	0	0	0	0	0	0	0
					4	0	0	0	0	0	0	0	0	0	0
Thyroid						<5>	<0>	<0>	<5>	<5>	<0>	<0>	<0>	<5>	<5>
Ectopic thymic tissue					1	1	0	0	0	0	0	0	0	0	0
					2	0	0	0	0	0	0	0	0	0	0
					3	0	0	0	0	0	0	0	0	0	0
					4	0	0	0	0	0	0	0	0	0	0
Ultimobranchial remnant						2	2	0	0	0	0	0	0	2	0
					2	0	0	0	0	0	0	0	0	0	0
					3	0	0	0	0	0	0	0	0	0	0
					4	0	0	0	0	0	0	0	0	0	0
Parathyroid						<5>	<0>	<0>	<5>	<5>	<0>	<0>	<0>	<5>	<5>
Adrenal						<5>	<0>	<0>	<5>	<5>	<0>	<0>	<0>	<5>	<5>
Accessory adrenocortical tissue					1	1	0	0	0	0	0	0	0	1	0
					2	0	0	0	0	0	0	0	0	0	0
					3	0	0	0	0	0	0	0	0	0	0
					4	0	0	0	0	0	0	0	0	0	0

◇, Number of animals examined
 1, Minimal; 2, Mild; 3, Moderate; 4, Severe

Table 38 Histological Findings - Summary

Organ Findings	Sex	Test Substance	Scheduled Sacrifice									
			Male			Female						
			CCH mg/kg	CCH mg/kg	CCH mg/kg	CCH mg/kg	CCH mg/kg	CCH mg/kg				
		Dose	7	12	60	12	300	7	12	60	12	300
		Dose Unit	7	12	12	12	7	7	12	12	12	12
		Number of Animals	7	12	12	12	7	7	12	12	12	12
		Grade	<5>	<0>	<0>	<0>	<5>	<5>	<5>	<0>	<0>	<5>
Adrenal		Fatty change, fascicular zone, focal	1				0	0	0	0	0	0
			2				0	0	0	0	0	0
			3				0	0	0	0	0	0
			4				0	0	0	0	0	0
Brain			<5>	<0>	<0>	<0>	<5>	<5>	<5>	<0>	<0>	<5>
Spinal cord			<5>	<0>	<0>	<0>	<5>	<5>	<5>	<0>	<0>	<5>
Sciatic nerve			<5>	<0>	<0>	<0>	<5>	<5>	<5>	<0>	<0>	<5>

◇, Number of animals examined.

1, Minimal; 2, Mild; 3, Moderate; 4, Severe

Table 38 Histological Findings - Summary

Not delivery and Total litter loss

Organ Findings	Sex	Test Substance	Male		Female		CCH mg/kg	CCH mg/kg	CCH mg/kg	CCH mg/kg
			CCH mg/kg	Number of Animals	CCH mg/kg	Number of Animals				
Thymus Atrophy			CCH mg/kg	Grade	CCH mg/kg	Grade	CCH mg/kg	Grade	CCH mg/kg	Grade
		0	7	<0>	60	12	<0>	10	12	<0>
		300	7	<0>	300	7	<0>	60	12	<1>
		300	7	<0>	300	7	<0>	300	12	<0>
Ovary Cell infiltration, inflammatory, bursa			CCH mg/kg	Grade	CCH mg/kg	Grade	CCH mg/kg	Grade	CCH mg/kg	Grade
		0	7	<0>	60	12	<0>	10	12	<1>
		300	7	<0>	300	7	<0>	60	12	<0>
		300	7	<0>	300	7	<0>	300	12	<0>
Dilatation, bursa			CCH mg/kg	Grade	CCH mg/kg	Grade	CCH mg/kg	Grade	CCH mg/kg	Grade
		0	7	<0>	60	12	<0>	10	12	<1>
		300	7	<0>	300	7	<0>	60	12	<0>
		300	7	<0>	300	7	<0>	300	12	<0>
Necrosis, luteal cell, unilateral			CCH mg/kg	Grade	CCH mg/kg	Grade	CCH mg/kg	Grade	CCH mg/kg	Grade
		0	7	<0>	60	12	<0>	10	12	<1>
		300	7	<0>	300	7	<0>	60	12	<0>
		300	7	<0>	300	7	<0>	300	12	<0>

◇, Number of animals examined
1, Minimal; 2, Mild; 3, Moderate; 4, Severe

Table 88 Histological Findings - Summary

Organ Findings	Sex	Male		Female		Scheduled Sacrifice (Recovery)	
		CCH	mg/kg	CCH	mg/kg	CCH	mg/kg
Testis							
Atrophy, seminiferous tubular epithelium		<0>		<1>			
	Grade						
	1			0			
	2			1			
	3			0			
	4			0			
	Number of Animals						
	Dose Unit						
	Dose	0		300		300	
	Test Substance	CCH		CCH		CCH	

◇, Number of animals examined
 1, Minimal; 2, Mild; 3, Moderate; 4, Severe

Table 38 Histological Findings - Summary

Organ Findings	Sex	Test Substance	Dose	Dose Unit	Number of Animals	Scheduled Sacrifice (Recovery)			
						Male		Female	
						CCH	CCH	CCH	CCH
						mg/kg	mg/kg	mg/kg	mg/kg
					Grade				
Kidney						<5>	<5>	<0>	<0>
Basophilic tubule, proximal tubule					1	2	2		
					2	0	0		
					3	0	0		
					4	0	0		
Cell infiltration, inflammatory, pelvis					1	1	0		
					2	0	0		
					3	0	0		
					4	0	0		
Hyaline droplet, proximal tubular epithelium					1	1	1		
					2	0	0		
					3	0	0		
					4	0	0		
Urinary bladder						<5>	<5>	<5>	<5>
Cell infiltration, lymphocyte, lamina propria					1	0	1	1	1
					2	0	0	0	0
					3	0	0	0	0
					4	0	0	0	0
Hyperplasia, mucosal epithelium					1	0	0	0	3
					2	0	0	0	0
					3	0	0	0	0
					4	0	0	0	0

◇, Number of animals examined
 1, Minimal; 2, Mild; 3, Moderate; 4, Severe

Table 39

Study No. B041794

 Reproductive Performance (F0) - Summary
 Mating Stage : 1st

Test Substance Dose (mg/kg)	Mean S.D. n	Number of Pairs	Mean Estrus Cycle	Incidence of Females with Irregular Estrus Cycle	Mating Period			Fertility Index (%)
					Number of Estrus	Day of Conceiving	Copulation Index (%) ^{a)}	
CCH M F	4.13 0.31 12	12	0/12	0/12	0.0 0.0 12	3.0 3.3 12	100.0 a) (12/12) b) (12/12)	100.0 (12/12)
CCH M F	4.08 0.29 12	12	0/12	0/12	0.1 0.3 12	3.7 4.2 12	100.0 (12/12)	100.0 (12/12)
CCH M F	4.25 0.45 12	12	0/12	0/12	0.0 0.0 12	2.9 3.4 12	100.0 (12/12)	100.0 (12/12)
CCH M F	4.00 0.00 12	12	0/12	0/12	0.0 0.0 12	2.8 1.3 12	100.0 (12/12)	100.0 (12/12)

a): Number of copulated females / Number of pairs
 b): Number of pregnant females / Number of copulated females
 Significantly different from control : *, P<0.05; **, P<0.01.

Table 40

Study No. B041794

Delivery Data (FO) - Summary

Test Substance Dose (mg/kg)	Mean S.D. n	Gestation Length (days)	Number of Corpora Lutea	Number of Implantation Sites	Total Number of Offspring	Implantation Index (%)	Delivery Index (%)	Gestation Index (%)
CCH 0	Mean	22.8	16.7	15.4	14.1	92.88	91.40	100.0
	S.D.	0.4	2.1	1.7	1.7	7.07	5.53	(12/12) a)
CCH 10	Mean	22.6	15.9	13.9	12.8	86.63	88.97	91.7
	S.D.	0.5	2.1	3.3	4.8	12.93	28.21	(11/12)
CCH 60	Mean	22.7	15.5	14.4	14.0	92.75	96.82	100.0
	S.D.	0.5	2.8	2.9	3.0	7.54	4.13	(12/12)
CCH 300	Mean	22.6	15.8	15.2	14.3	95.88	94.23	100.0
	S.D.	0.5	1.6	1.5	1.2	4.06	6.02	(12/12)

a): Number of pregnant animals delivered live offspring / number of pregnant animals
Significantly different from control : *, $P < 0.05$; **, $P < 0.01$.

Table 41

Study No. B041794

Litter Size and Viability Index (FI) - Summary

Test Substance Dose (mg/kg)	Mean S.D. n (M/F)	Total Number of Offspring at Birth		Number of Live Offspring at Birth		Number of Live Offspring on Day 4 before Culling			Number of Live Offspring on Day 5			Viability Index (%)		
		M	F	M	F	M	F	Total	M	F	Total	Day 0	Day 4	Day 5
		Total	Total	Total	Total	Total	Total	Total	Total	Total	Total	Total	Total	Total
CCH 0	6.8	7.3	14.1	6.5	7.3	6.3	7.3	13.6	6.3	7.3	13.6	98.20	98.33	
	1.6 1.2 (81/88)	2.1 1.2 (78/88)	1.7 1.2 (81/88)	2.1 1.2 (78/88)	1.9 1.2 (88/88)	2.1 1.2 (75/88)	2.1 1.2 (75/88)	1.7 1.2 (88/88)	1.7 1.2 (88/88)	1.7 1.2 (88/88)	1.7 1.2 (88/88)	4.34 1.2 (88/88)	3.02 1.2 (88/88)	
CCH 10	8.0	6.0	14.0	8.0	6.0	7.9	5.9	13.8	7.9	5.9	13.8	100.00	98.75	
	2.9 1.1 (88/66)	1.9 1.1 (88/66)*	2.7 1.1 (88/66)	1.9 1.1 (88/66)*	2.7 1.1 (87/65)	2.0 1.1 (87/65)	2.0 1.1 (87/65)	2.7 1.1 (87/65)	2.7 1.1 (87/65)	2.7 1.1 (87/65)	2.7 1.1 (87/65)	0.00 1.1 (87/65)	2.79 1.1 (87/65)	
CCH 60	6.3	7.8	14.0	6.0	7.5	5.5	7.0	12.5	5.5	7.0	12.5	97.06	91.11	
	2.6 1.2 (75/93)	2.1 1.2 (75/93)	3.0 1.2 (75/93)	2.2 1.2 (72/90)	2.2 1.2 (72/90)	3.0 1.2 (66/84)	3.0 1.2 (66/84)	4.9 1.2 (66/84)	3.0 1.2 (66/84)	3.0 1.2 (66/84)	4.9 1.2 (66/84)	10.19 1.2 (66/84)	28.76 1.2 (66/84)	
CCH 300	8.0	6.3	14.3	7.9	6.3	7.9	6.2	14.1	7.9	6.2	14.1	99.48	99.44	
	1.5 1.2 (96/75)	1.7 1.2 (96/75)	1.2 1.2 (96/75)	1.4 1.2 (95/75)	1.7 1.2 (95/75)	1.4 1.2 (95/74)	1.7 1.2 (95/74)*	1.1 1.2 (95/74)	1.4 1.2 (95/74)	1.7 1.2 (95/74)	1.1 1.2 (95/74)	1.79 1.2 (95/74)	1.93 1.2 (95/74)	

Significantly different from control

: *P<0.05; **P<0.01.

Table 42

Clinical Sign (Fl before Weaning) - Summary
 Stage : Before Culling

Test Substance Dose (mg/kg)	Findings (M/F)	Day				
		0	1	2	3	4
CCH 0	Number of dams	12	12	12	12	12
	Number of offspring	81/88/0	78/88	78/88	78/88	77/88
	Number of dams with abnormal offspring	0	0	0	0	0
	No Abnormality Death (M/F/U)	78/88 3/0/0	78/88 0/0	78/88 0/0	77/88 1/0	75/88 2/0
CCH 10	Number of dams	11	11	11	11	11
	Number of offspring	88/66/0	88/66	88/65	88/65	87/65
	Number of dams with abnormal offspring	0	0	0	0	0
	No Abnormality Death (M/F/U)	88/66 0/0/0	88/65 0/1	88/65 0/0	87/65 1/0	87/65 0/0
CCH 60	Number of dams	12	12	12	11	11
	Number of offspring	75/93/0	72/90	70/87	66/84	66/84
	Number of dams with abnormal offspring	1	1	0	0	0
	No Abnormality Death (M/F/U)	67/85 3/3/0	66/84 2/3	66/84 4/3	66/84 0/0	66/84 0/0
	Loss of suckling	5/5	4/3			
CCH 300	Number of dams	12	12	12	12	12
	Number of offspring	96/75/0	95/75	95/75	95/75	95/75
	Number of dams with abnormal offspring	0	0	0	0	0
	No Abnormality Death (M/F/U)	95/75 1/0/0	95/75 0/0	95/75 0/0	95/75 0/0	95/74 0/1

M:Male, F:Female, U:Unable to be sexed on day 0

Table 43

Study No. B041794

Body Weight of Offspring (F1 before Weaning) - Summary
Sex : Male

Test Substance Dose (mg/kg)	before Culling		/ after Culling	
	Mean S.D. n	0	4	4
CCH 0	7.3 0.6 12	11.9 1.3 12		
CCH 10	7.1 0.8 11	11.7 1.6 11		
CCH 60	7.1 0.7 12	11.8 1.8 11		
CCH 300	6.6 0.6 12	10.4 1.3 12		

Significantly different from control

: *, P<0.05; **, P<0.01.

Table 43

Study No. B041794

Body Weight of Offspring (F1 before Weaning) - Summary
Sex : Female

Test Substance Dose (mg/kg)	/Day		before Culling		/ after Culling		Unit : g	
	0	4	Mean	S.D.	n	Mean		S.D.
CCH 0	7.0	11.4	0.5	1.2	12	0.8	1.7	11
CCH 10	6.6	11.0	0.8	1.7	11	6.7	1.3	11
CCH 60	6.7	11.3	0.7	1.7	12	6.2	1.0	12
CCH 300	6.2	10.0	0.7	1.2	12			

Significantly different from control

: *, P<0.05; **, P<0.01.

Table 44

Study No. B041794

Body Weight Gain of Offspring (P1 before Weaning) - Summary
 Sex : Male
 Base : Day 4 after Birth

Unit : g

Test Substance Dose (mg/kg)	before Culling		after Culling	
	Mean S.D. n	0 - 4 /Day	Mean S.D. n	0 - 4 /Day
CCH 0	4.6 0.8 12		4.6 0.9 11	
CCH 10	4.6 0.9 11		4.6 1.2 11	
CCH 60	4.6 0.9 11		3.9 0.7 12	
CCH 300	4.6 0.9 11		3.9 0.7 12	

Significantly different from control : * , P<0.05; ** , P<0.01.

Table 44

Study No. B041794

Body Weight Gain of Offspring (F1 before Weaning) - Summary
 Sex: Female Base: Day 4 after Birth

Test Substance Dose (mg/kg)	/Day	before Culling		after Culling	
		0 - 4			
CCH 0	Mean	4.4			
	S.D. n	0.8 12			
CCH 10	Mean	4.3			
	S.D. n	1.0 11			
CCH 60	Mean	4.4			
	S.D. n	1.2 11			
CCH 300	Mean	3.8			
	S.D. n	0.7 12			

Significantly different from control : *, P<0.05; **, P<0.01.

Table 45

Study No. B041794

External Examination of Offspring (F1) - Summary
Day : 0 (Birth Day)

Test Substance	CCH	CCH	CCH	CCH	CCH
Dose (mg/kg)	0	10	10	60	300
Number of Dams	12	11	11	12	12
Number of Offspring	166	154	154	162	170
Number of Dams with Anomalous Offspring	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (8.3%)	0 (0.0%)
Number of Offspring with Any Anomalies	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)
Anal atresia	a) 0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Mean	0.0	0.0	0.0	0.6	0.0
S.D.	0.0	0.0	0.0	2.2	0.0
Anury	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Mean	0.0	0.0	0.0	0.6	0.0
S.D.	0.0	0.0	0.0	2.2	0.0

a) : Number of anomalous offspring (number of dams with anomalous offspring)

b) : Number of anomalous offspring / number of offspring examined x 100 (%), on litter basis

Significantly different from control ; *, p<0.05; **, p<0.01.

Table 46

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Necropsy Findings (F1 Offspring)
Test Substance : CCH

Test Substance Dose.(mg/kg)	/Findings	Day:	Scheduled Sacrifice		Dead		Dead		Dead		Dead	
			M	F	M	F	M	F	M	F	M	F
CCH 0	Number of offspring examined No abnormality		75	88	0		1		2		3	
			75	88	3	3	1	1	2	2	3	4
CCH 10	Number of offspring examined No abnormality		87	65								
			87	65								
CCH 60	Number of offspring examined No abnormality		66	84			2		4		3	
			66	84	3	3	2	2	4	4	3	3
CCH 300	Number of offspring examined No abnormality		95	74	1							
			95	74	1	1						

M:Male, F:Female