

Table 7 Detailed Clinical Observations - Summary (Week 4)

Items	Sex: Test Substance: Dose (mg/kg): Number of Animals:	Male				Female			
		CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH
		0	10	60	300	0	10	60	300
		12	12	12	12	17	12	12	17
Open field observations	(Criteria)								
Clonic convulsion	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
Tonic convulsion	N	12	12	12	12	17	12	12	17
	1	0	0	0	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
	5	0	0	0	0	0	0	0	0
Stereotypy	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0
Bizarre behaviour	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0

See Annex 12.7 for details of criteria.

Table 7 Detailed Clinical Observations - Summary (Week 5)

Items	Sex: Test Substance: Dose (mg/kg): Number of Animals:	Male				Female			
		CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH
		0	10	60	300	0	10	60	300
		12	12	12	12	17	12	12	17
Home cage observations	(Criteria)								
Tremor	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
Clonic convulsion	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
Tonic convulsion	N	12	12	12	12	17	12	12	17
	1	0	0	0	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
	5	0	0	0	0	0	0	0	0
Breathing	N	12	12	12	12	17	12	12	17
	1	0	0	0	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
	5	0	0	0	0	0	0	0	0
Hand-held observations									
Reactivity on removal	1	0	0	0	0	0	0	0	0
from the cage	2	12	12	12	12	17	12	12	17
	3	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0
	6	0	0	0	0	0	0	0	0

See Annex 12.7 for details of criteria.

Table 7 Detailed Clinical Observations - Summary (Week 5)

Items	Sex:	Male				Female			
		CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH
	Test Substance:	0	10	60	300	0	10	60	300
	Dose (mg/kg):	12	12	12	12	17	12	12	17
	Number of Animals:								
Hand-held observations	(Criteria)								
Reactivity to handling	1	0	0	0	0	0	0	0	0
	2	12	12	12	12	17	12	12	17
	3	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0
Aggression	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0
Trauma	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0
Color of skin	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
Soiled fur	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0
Exophthalmos	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0
Palpebral closure	1	12	12	12	12	17	12	12	17
	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
Color of conjunctiva	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
Secretion	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0

See Annex 12.7 for details of criteria.

Table 7 Detailed Clinical Observations - Summary (Week 5)

Items	Sex: Test Substance: Dose (mg/kg): Number of Animals:	Male				Female			
		CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH
		0	10	60	300	0	10	60	300
		12	12	12	12	17	12	12	17
Hand-held observations	(Criteria)								
Lacrimation	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0
Salivation	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0
Piloerection	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0
Pupil size	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
Open field observations									
Rearing	Mean	3.4	3.4	2.8	5.6	5.3	5.8	7.0	4.7
	S. D.	4.1	3.1	4.8	2.5	4.4	4.6	3.0	3.4
Arousal	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
	3	12	12	12	12	17	12	12	17
	4	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0
Urination	N	12	11	11	12	15	12	10	13
	P	0	1	1	0	2	0	2	4

See Annex 12.7 for details of criteria.

Table 7 Detailed Clinical Observations - Summary (Week 5)

Items	Sex:	Male				Female			
		CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH
	Test Substance:	0	10	60	300	0	10	60	300
	Dose (mg/kg):	0	10	60	300	0	10	60	300
	Number of Animals:	12	12	12	12	17	12	12	17
Open field observations	(Criteria)								
Defecation	N	9	12	11	12	16	12	12	17
	P	3	0	1	0	1	0	0	0
Posture, body position	N	12	12	12	12	17	12	12	17
	1	0	0	0	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
	5	0	0	0	0	0	0	0	0
Breathing	N	12	12	12	12	17	12	12	17
	1	0	0	0	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
	5	0	0	0	0	0	0	0	0
Co-ordination movement	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0
Gait	N	12	12	12	12	17	12	12	17
	1	0	0	0	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
	5	0	0	0	0	0	0	0	0
	6	0	0	0	0	0	0	0	0
	7	0	0	0	0	0	0	0	0
Tremor	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0

See Annex 12.7 for details of criteria.

Table 7 Detailed Clinical Observations - Summary (Week 5)

Items	Sex: Test Substance: Dose (mg/kg): Number of Animals:	Male				Female			
		CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH
		0	10	60	300	0	10	60	300
		12	12	12	12	17	12	12	17
Open field observations	(Criteria)								
Clonic convulsion	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
Tonic convulsion	N	12	12	12	12	17	12	12	17
	1	0	0	0	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
	5	0	0	0	0	0	0	0	0
Stereotypy	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0
Bizarre behaviour	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0

See Annex 12.7 for details of criteria.

Table 7 Detailed Clinical Observations - Summary (Week 6)

Items	Sex: Test Substance: Dose (mg/kg): Number of Animals:	Male				Female			
		CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH
		0	10	60	300	0	10	60	300
		12	12	12	12	17	12	12	17
Home cage observations	(Criteria)								
Tremor	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
Clonic convulsion	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
Tonic convulsion	N	12	12	12	12	17	12	12	17
	1	0	0	0	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
	5	0	0	0	0	0	0	0	0
Breathing	N	12	12	12	12	17	12	12	17
	1	0	0	0	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
	5	0	0	0	0	0	0	0	0
Hand-held observations									
Reactivity on removal	1	0	0	0	0	0	0	0	0
from the cage	2	12	12	12	12	17	12	12	17
	3	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0
	6	0	0	0	0	0	0	0	0

See Annex 12.7 for details of criteria.

Table 7 Detailed Clinical Observations - Summary (Week 6)

Items	Sex:	Male				Female			
		CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH
	Test Substance:	0	10	60	300	0	10	60	300
	Dose (mg/kg):	0	10	60	300	0	10	60	300
	Number of Animals:	12	12	12	12	17	12	12	17
Hand-held observations	(Criteria)								
Reactivity to handling	1	0	0	0	0	0	0	0	0
	2	12	12	12	12	17	12	12	17
	3	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0
Aggression	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0
Trauma	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0
Color of skin	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
Soiled fur	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0
Exophthalmos	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0
Palpebral closure	1	12	12	12	12	17	12	12	17
	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
Color of conjunctiva	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
Secretion	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0

See Annex 12.7 for details of criteria.

Table 7 Detailed Clinical Observations - Summary (Week 6)

Items	Sex: Test Substance: Dose (mg/kg): Number of Animals:	Male				Female			
		CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH
		0	10	60	300	0	10	60	300
		12	12	12	12	17	12	12	17
Hand-held observations	(Criteria)								
Lacrimation	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0
Salivation	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0
Piloerection	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0
Pupil size	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
Open field observations									
Rearing	Mean	5.8	5.1	3.0	3.7	6.9	7.8	8.0	6.5
	S. D.	4.5	3.7	2.4	4.0	3.3	3.9	3.9	4.3
Arousal	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
	3	12	12	12	12	17	12	12	17
	4	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0
Urination	N	11	11	11	12	15	11	12	15
	P	1	1	1	0	2	1	0	2

See Annex 12.7 for details of criteria.

Table 7 Detailed Clinical Observations - Summary (Week 6)

Items	Sex:	Male				Female			
		CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH
	Test Substance:	0	10	60	300	0	10	60	300
	Dose (mg/kg):								
	Number of Animals:	12	12	12	12	17	12	12	17
Open field observations	(Criteria)								
Defecation	N	10	11	11	11	17	12	12	17
	P	2	1	1	1	0	0	0	0
Posture, body position	N	12	12	12	12	17	12	12	17
	1	0	0	0	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
	5	0	0	0	0	0	0	0	0
Breathing	N	12	12	12	12	17	12	12	17
	1	0	0	0	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
	5	0	0	0	0	0	0	0	0
Co-ordination movement	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0
Gait	N	12	12	12	12	17	12	12	17
	1	0	0	0	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
	5	0	0	0	0	0	0	0	0
	6	0	0	0	0	0	0	0	0
	7	0	0	0	0	0	0	0	0
Tremor	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0

See Annex 12.7 for details of criteria.

Table 7 Detailed Clinical Observations - Summary (Week 6)

Items	Sex:	Male				Female			
		CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH
	Test Substance:	0	10	60	300	0	10	60	300
	Dose (mg/kg):	0	10	60	300	0	10	60	300
	Number of Animals:	12	12	12	12	17	12	12	17
Open field observations	(Criteria)								
Clonic convulsion	N	12	12	12	12	17	12	12	17
	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
Tonic convulsion	N	12	12	12	12	17	12	12	17
	1	0	0	0	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
	5	0	0	0	0	0	0	0	0
Stereotypy	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0
Bizarre behaviour	N	12	12	12	12	17	12	12	17
	P	0	0	0	0	0	0	0	0

See Annex 12.7 for details of criteria.

Table 8 Functional Tests - Summary

(Week 6)

Items	Sex: Test Substance: Dose (mg/kg): Number of Animals:	Male				Female			
		CCH	CCH	CCH	CCH	CCH	CCH	CCH	CCH
		0	10	60	300	0	10	60	300
		5	5	5	5	5	5	5	5
Sensory reactivity to stimuli (Criteria)									
Approach response	1	0	0	0	0	0	0	0	0
	2	5	5	4	4	5	5	5	5
	3	0	0	1	1	0	0	0	0
	4	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0
Touch response	1	0	0	0	0	0	0	0	0
	2	4	4	3	1	5	5	4	5
	3	1	1	2	4	0	0	1	0
	4	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0
Auditory response	1	0	0	0	0	0	0	0	0
	2	5	5	5	5	5	5	5	5
	3	0	0	0	0	0	0	0	0
Tail pinch response	1	0	0	0	0	0	0	0	0
	2	5	5	4	5	5	5	5	5
	3	0	0	1	0	0	0	0	0
	4	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0
Aerial righting reaction	1	5	5	5	5	5	5	5	5
	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
Grip strength									
Forelimb grip strength	Mean (g)	1541.6	1278.8	1394.0	1244.6	1112.6	1080.4	1065.8	929.4
	S. D.	136.4	83.8	241.3	195.8	198.9	199.1	106.2	178.9
Hindlimb grip strength	Mean (g)	841.8	837.0	829.4	823.0	618.4	585.6	639.6	605.6
	S. D.	25.7	65.0	53.8	92.3	84.3	33.3	124.7	92.4

Significantly different from control : *, P<0.05 ; **, P<0.01
See Annex 12.7 for details of criteria.

Table 9 Motor Activity - Summary

(Week 6)

Male

Test Substance	Time:	0-10 min	10-20 min	20-30 min	30-40min	40-50min	50-60min	Total
Dose (mg/kg)	Unit:	Count/10 min	Count/10 min	Count/10 min	Count/10 min	Count/10 min	Count/10 min	Count/1 hr
CCH 0	Mean	2557.0	1507.2	680.4	493.6	383.4	414.6	6036.2
	S. D.	575.4	927.3	559.3	948.5	762.9	811.4	4122.1
	n	5	5	5	5	5	5	5
CCH 10	Mean	2142.0	1073.4	218.6	100.8	23.2	6.6	3564.6
	S. D.	249.0	664.7	348.5	96.3	43.2	6.2	1054.5
	n	5	5	5	5	5	5	5
CCH 60	Mean	2213.2	756.0	182.2	33.0	72.0	37.2	3293.6
	S. D.	477	386.0	177.2	32.1	68.6	27.9	819.9
	n	5	5	5	5	5	5	5
CCH 300	Mean	1987.2	608.6	112.0	26.8	92.2	30.6	2857.4
	S. D.	449.8	532.1	91.9	28.2	101.5	29.3	955.7
	n	5	5	5	5	5	5	5

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

Table 10 Motor Activity - Summary

(Week 6)

Female

Test Substance	Time:	0-10 min	10-20 min	20-30 min	30-40min	40-50min	50-60min	Total
Dose (mg/kg)	Unit:	Count/10 min	Count/10 min	Count/10 min	Count/10 min	Count/10 min	Count/10 min	Count/1 hr
CCH 0	Mean	756.6	186.0	56.0	45.4	10.8	15.4	1070.2
	S. D.	721.2	374.9	35.4	28.5	11.5	15.8	1118.8
	n	5	5	5	5	5	5	5
CCH 10	Mean	1538.6	924.0	819.4	348.0	830.8	475.4	4936.2
	S. D.	502.4	623.6	1084.5	519.3	1118.3	430.9	3627.0
	n	5	5	5	5	5	5	5
CCH 60	Mean	1127.6	452.0	65.4	259.4	312.2	464.4	2681.0
	S. D.	482.4	600.7	42.6	444.4	499.8	781.3	1831.3
	n	5	5	5	5	5	5	5
CCH 300	Mean	1459.2	562.8	243.4	380.4	9.6	26.8	2682.2
	S. D.	512.3	756.7	406.3	745.7	13.3	36.4	1972.4
	n	5	5	5	5	5	5	5

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

Table 11 Body Weight - Summary

Test Substance Dose(mg/kg)	Day	Male									
		1	8	15	22	29	36	42	43	50	56
CCH 0	Mean	352.1	385.3	414.5	438.3	463.3	487.2	501.6	497.2	510.2	529.0
	S.D.	16.9	22.0	23.3	23.3	27.9	30.2	30.7	21.3	17.6	21.6
	n	12	12	12	12	12	12	12	5	5	5
CCH 10	Mean	348.3	383.3	415.4	445.3	471.8	496.3	513.3			
	S.D.	16.3	17.5	21.2	25.9	29.2	32.7	36.5			
	n	12	12	12	12	12	12	12			
CCH 60	Mean	350.7	380.3	410.4	435.7	462.9	488.3	504.6			
	S.D.	18.0	25.2	31.4	32.0	37.3	42.8	46.2			
	n	12	12	12	12	12	12	12			
CCH 300	Mean	349.8	373.0	399.1	417.8	440.1	459.4	473.3	482.8	506.4	535.4
	S.D.	13.9	20.9	25.7	27.2	29.7	30.6	32.2	38.9	39.7	47.5
	n	12	12	12	12	12	12	12	5	5	5

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

Table 12 Body Weight - Summary

Female

Test Substance	Dose (mg/kg)	Day	1	8	15
CCH	0	Mean	215.0	230.2	245.7
		S. D.	8.8	9.6	14.6
		n	17	17	17
CCH	10	Mean	212.3	227.9	245.7
		S. D.	6.0	12.7	18.5
		n	12	12	12
CCH	60	Mean	212.5	228.4	241.2
		S. D.	10.3	9.5	14.9
		n	12	12	12
CCH	300	Mean	211.9	225.5	234.7
		S. D.	8.9	9.9	11.3
		n	17	17	17

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

Table 13

Study No. B041794

Body Weight (F0 Gestation) - Summary

Unit : g

Test Substance Dose (mg/kg)	/Day	0	7	14	20
CCH 0	Mean	253.8	295.6	332.8	414.8
	S. D.	17.3	19.9	23.7	31.1
	n	12	12	12	12
CCH 10	Mean	257.5	296.9	331.2	405.9
	S. D.	23.7	22.6	22.6	29.2
	n	12	12	12	12
CCH 60	Mean	251.9	294.8	334.6	417.0
	S. D.	21.9	17.7	16.8	25.2
	n	12	12	12	12
CCH 300	Mean	243.1	278.4	313.2	389.8
	S. D.	13.3	17.6	22.0	27.7
	n	12	12	12	12

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

Table 14

Study No. B041794

Body Weight (F0 Lactation) - Summary

Unit : g

Test Substance Dose (mg/kg)		/Day	0	4
CCH	0	Mean	315.1	334.7
		S. D.	27.1	23.0
		n	12	12
CCH	10	Mean	316.5	324.9
		S. D.	19.3	23.8
		n	11	11
CCH	60	Mean	319.4	330.4
		S. D.	20.3	16.4
		n	12	11
CCH	300	Mean	299.4	313.0
		S. D.	20.1	22.8
		n	12	12

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

Table 15 Body Weight - Summary

Female #

Study No. B041794
Unit : g

Test Substance Dose (mg/kg)	Day	22	29	36	42	43	50	56
CCH 0	Mean	263.4	269.0	279.8	295.4	294.8	303.4	308.8
	S. D.	18.6	19.7	16.6	20.0	18.8	20.2	18.5
	n	5	5	5	5	5	5	5
CCH 300	Mean	246.6	254.0	265.0	275.8	276.8	291.8	306.2
	S. D.	9.3	8.1	6.0	7.0	6.9	9.6	11.1
	n	5	5	5	5	5	5	5

Significantly different from control
#:Satellite animal

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

Table 16 Accumulative Body Weight Gain - Summary

Male

Test Substance	Day	1	8	15	22	29	36	42	43	50	56
CCH 0	Mean	0.0	33.2	62.4	86.3	111.3	135.1	149.5	151.4	164.4	183.2
	S. D.	0.0	10.0	11.1	10.7	13.8	17.0	17.6	15.1	10.7	11.0
	n	12	12	12	12	12	12	12	5	5	5
CCH 10	Mean	0.0	35.0	67.1	97.0	123.4	147.9	165.0			
	S. D.	0.0	6.6	11.5	16.1	19.1	22.4	26.3			
	n	12	12	12	12	12	12	12			
CCH 60	Mean	0.0	29.7	59.8	85.0	112.3	137.7	153.9			
	S. D.	0.0	9.2	16.3	18.4	24.5	28.7	31.5			
	n	12	12	12	12	12	12	12			
CCH 300	Mean	0.0	23.2*	49.3	67.9*	90.3*	109.6*	123.5*	130.0	153.6	182.6
	S. D.	0.0	10.2	15.8	17.3	20.8	21.3	23.0	19.7	19.7	27.9
	n	12	12	12	12	12	12	12	5	5	5

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

Table 17 Accumulative Body Weight Gain - Summary Female

Test Substance	Dose (mg/kg)	Day	1	8	15
CCH	0	Mean	0.0	15.2	30.7
		S. D.	0.0	6.5	10.8
		n	17	17	17
CCH	10	Mean	0.0	15.7	33.4
		S. D.	0.0	8.4	14.0
		n	12	12	12
CCH	60	Mean	0.0	15.9	28.7
		S. D.	0.0	4.7	9.0
		n	12	12	12
CCH	300	Mean	0.0	13.6	22.8*
		S. D.	0.0	6.8	6.2
		n	17	17	17

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

Table 18

Study No. B041794

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

Unit : g

Test Substance Dose (mg/kg)	/Day	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	146.7
	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		/Day	0	4
Dose (mg/kg)				
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.

Table 20 Accumulative Body Weight Gain - Summary

Female #

Study No. B041794
Unit : g

Test Substance Dose(mg/kg)	Day	22	29	36	42	43	50	56
CCH 0	Mean	0.0	5.6	16.4	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	22.63	21.79	26.92	26.00
	S.D.	2.20	1.50		1.22	1.22	1.89	1.33	1.22
	n	12	12		11	12	12	5	5
CCH 10	Mean	24.05	22.47		23.29	23.46	22.67		
	S.D.	2.21	2.18		2.21	2.46	1.91		
	n	12	12		10	12	12		
CCH 60	Mean	23.55	21.68		22.40	23.23	23.29		
	S.D.	2.08	2.36		2.01	2.00	2.66		
	n	12	12		11	12	12		
CCH 300	Mean	23.17	22.02		22.43	23.23	23.08	28.90	29.10
	S.D.	2.28	2.09		1.76	2.10	2.41	3.62	3.71
	n	12	12		12	12	12	5	5

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

Table 22 Food Consumption - Summary

Female

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

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

Table 23

Study No. B041794

Food Consumption (F0 Gestation) - Summary

Unit : g/animal/day

Test Substance Dose (mg/kg)		/Day	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

Unit : g/animal/day

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

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

Table 25 Food Consumption - Summary

Female #

Study No. B041794
Unit : g/animal/day

Test Substance Dose (mg/kg)	Day	22	29	36	42	50	56
CCH 0	Mean	17.02	16.20	16.96	16.46	20.36	20.28
	S. D.	1.85	1.61	2.00	1.31	2.15	1.76
	n	5	5	5	5	5	5
CCH 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

Table 26 Hematology - Summary

Male

Test Substance Dose(mg/kg)		Red Blood Cell Count x10E6/ μ L		Hemoglobin conc. g/dL		Hematocrit %		MCV fL		MCH pg		MCHC %		Platelet Count x10E3/ μ L		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 S.D. n	8.298 0.118 5	8.548 0.224 5	15.58 0.27 5	15.38 0.26 5	45.48 0.84 5	45.36 1.19 5	54.80 1.34 5	53.12 2.54 5	18.74 0.45 5	18.00 0.52 5	34.24 0.22 5	33.94 0.72 5	1055.6 163.6 5	970.4 73.1 5	2.58 0.13 5	2.64 0.11 5
CCH	10	Mean S.D. n	8.618 0.203 5		15.46 0.51 5		45.88 1.14 5		53.26 0.84 5		17.94 0.39 5		33.68 0.60 5		972.0 131.7 5		2.40 0.57 5		21.90 1.90 5	
CCH	60	Mean S.D. n	8.318 0.219 5		15.32 0.31 5		44.96 1.36 5		54.06 0.36 5		18.44 0.18 5		34.10 0.45 5		974.8 93.4 5		2.48 0.29 5		25.16 4.83 5	
CCH	300	Mean S.D. n	8.512 0.487 5	8.440 0.285 5	15.42 0.54 5	15.12 0.46 5	45.40 1.80 5	44.14 1.37 5	53.44 2.24 5	52.32 1.82 5	18.14 0.84 5	17.94 0.44 5	33.94 0.38 5	34.26 0.57 5	985.8 104.4 5	1013.0 89.6 5	3.26* 0.35 5	2.30* 0.23 5	20.72 2.30 5	25.22 3.94 5

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

Table 26 Hematology - Summary

Male

Test Substance		APTT	
Dose (mg/kg)		sec	
		Day 43	Day 57
CCH	Mean	22.88	20.98
	0 S. D.	2.35	1.58
	n	5	5
CCH	Mean	21.46	
	10 S. D.	1.79	
	n	5	
CCH	Mean	23.78	
	60 S. D.	3.17	
	n	5	
CCH	Mean	20.24	21.48
	300 S. D.	1.67	2.75
	n	5	5

Significantly different from control

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

Table 26 Hematology - Summary

Male

Test Substance Dose(mg/kg)		White Blood Cell Count x10E3/ μ L	
		Day 43	Day 57
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	7.536
	S. D.	1.353	0.731
	n	5	5

Significantly different from control

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

Table 26 Hematology - Summary

Test Substance Dose (mg/kg)		Male											
		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	89.16	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	4.37	4.97	0.00	0.00	0.71	0.89	0.00	0.00	1.64	1.96
	n	5	5	5	5	5	5	5	5	5	5	5	5
CCH 10	Mean	83.40		13.60		0.40		0.60		0.00		2.00	
	S. D.	2.41		1.14		0.55		0.55		0.00		1.58	
	n	5		5		5		5		5		5	
CCH 60	Mean	85.96		11.84		0.00		1.00		0.00		1.20	
	S. D.	3.68		3.18		0.00		1.22		0.00		0.84	
	n	5		5		5		5		5		5	
CCH 300	Mean	87.50	85.56	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	0.00	0.45	1.00
	n	5	5	5	5	5	5	5	5	5	5	5	5

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