

4-*tert*-ブチルカテコールのラットを用いた
経口投与による 13 週間毒性試験（混餌試験）報告書

試験番号：0719

TABLES

TABLES

TABLE A 1 SURVIVAL ANIMAL NUMBERS: MALE

TABLE A 2 SURVIVAL ANIMAL NUMBERS: FEMALE

TABLE B 1 CLINICAL OBSERVATION: MALE

TABLE B 2 CLINICAL OBSERVATION: FEMALE

TABLE C 1 BODY WEIGHT CHANGES AND SURVIVAL ANIMAL NUMBERS:
MALE

TABLE C 2 BODY WEIGHT CHANGES AND SURVIVAL ANIMAL NUMBERS:
FEMALE

TABLE C 3 BODY WEIGHT CHANGES: MALE

TABLE C 4 BODY WEIGHT CHANGES: FEMALE

TABLE D 1 FOOD CONSUMPTION CHANGES AND SURVIVAL ANIMAL
NUMBERS: MALE

TABLE D 2 FOOD CONSUMPTION CHANGES AND SURVIVAL ANIMAL
NUMBERS: FEMALE

TABLE D 3 FOOD CONSUMPTION CHANGES: MALE

TABLE D 4 FOOD CONSUMPTION CHANGES: FEMALE

TABLE E 1 CHEMICAL INTAKE CHANGES: MALE

TABLE E 2 CHEMICAL INTAKE CHANGES: FEMALE

TABLE F 1 HEMATOLOGY: MALE

TABLE F 2 HEMATOLOGY: FEMALE

TABLE G 1 BIOCHEMISTRY: MALE

TABLE G 2 BIOCHEMISTRY: FEMALE

TABLES (CONTINUED)

TABLE H 1 URINALYSIS: MALE

TABLE H 2 URINALYSIS: FEMALE

TABLE I 1 GROSS FINDINGS: MALE: ALL ANIMALS

TABLE I 2 GROSS FINDINGS: FEMALE: ALL ANIMALS

TABLE J 1 ORGAN WEIGHT, ABSOLUTE: MALE

TABLE J 2 ORGAN WEIGHT, ABSOLUTE: FEMALE

TABLE K 1 ORGAN WEIGHT, RELATIVE: MALE

TABLE K 2 ORGAN WEIGHT, RELATIVE: FEMALE

TABLE L 1 HISTOPATHOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS:
MALE: ALL ANIMALS

TABLE L 2 HISTOPATHOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS:
FEMALE: ALL ANIMALS

TABLE A 1

SURVIVAL ANIMAL NUMBERS: MALE

STUDY NO. : 0719
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1 13
SEX : MALE

SURVIVAL ANIMAL NUMBERS

PAGE : 1

Group Name	Animals At start	Administration (Weeks)													
		0	1	2	3	4	5	6	7	8	9	10	11	12	13
Control	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
256 ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
640 ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
1600 ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
4000 ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
10000 ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Number of survival/ Number of effective animals Survival rate(%)															

(HAN360)

BA1S4

TABLE A 2

SURVIVAL ANIMAL NUMBERS: FEMALE

STUDY NO. : 0719
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1 13
SEX : FEMALE

SURVIVAL ANIMAL NUMBERS

PAGE : 2

Group Name	Animals At start	Administration (Weeks)													
		0	1	2	3	4	5	6	7	8	9	10	11	12	13
Control	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
256 ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
640 ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
1600 ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
4000 ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
10000 ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Number of survival/ Number of effective animals															
Survival rate(%)															

(HAN360)

BAIS4

TABLE B 1

CLINICAL OBSERVATION: MALE

STUDY NO. : 0719
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE : 1

Clinical sign	Group Name	Administration Week-day												
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
NON REMARKABLE	Control	10	10	10	10	10	10	10	10	10	10	10	10	10
	256 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	640 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	1600 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	4000 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	10000 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10

(HAN190)

BAIS 4

TABLE B 2

CLINICAL OBSERVATION: FEMALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
 ALL ANIMALS

SEX : FEMALE

PAGE : 2

Clinical sign	Group Name	Administration Week-day												
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
SOILED PERI-GENITALIA	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	256 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	640 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	1600 ppm	0	0	0	0	0	2	2	2	1	1	1	1	1
	4000 ppm	0	0	2	1	1	6	6	6	5	5	5	4	3
	10000 ppm	1	1	6	6	6	10	10	10	10	9	8	8	3
NON REMARKABLE	Control	10	10	10	10	10	10	10	10	10	10	10	10	10
	256 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	640 ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	1600 ppm	10	10	10	10	10	8	8	8	9	9	9	9	9
	4000 ppm	10	10	8	9	9	4	4	4	5	5	5	6	7
	10000 ppm	9	9	4	4	4	0	0	0	0	1	2	2	7

(HAN190)

BATS 4

TABLE C 1

BODY WEIGHT CHANGES AND
SURVIVAL ANIMAL NUMBERS: MALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

MEAN BODY WEIGHTS AND SURVIVAL

PAGE : 1

Week on Study	Control			256 ppm			640 ppm			1600 ppm			4000 ppm			10000 ppm		
	Av. Wt.	No. of Surviv. <10>		Av. Wt.	% of cont. <10>	No. of Surviv.	Av. Wt.	% of cont. <10>	No. of Surviv.	Av. Wt.	% of cont. <10>	No. of Surviv.	Av. Wt.	% of cont. <10>	No. of Surviv.	Av. Wt.	% of cont. <10>	No. of Surviv.
0	120 (10)	10/10		120 (10)	100	10/10	120 (10)	100	10/10	120 (10)	100	10/10	120 (10)	100	10/10	120 (10)	100	10/10
1	149 (10)	10/10		150 (10)	101	10/10	151 (10)	101	10/10	150 (10)	101	10/10	143 (10)	96	10/10	131 (10)	88	10/10
2	182 (10)	10/10		185 (10)	102	10/10	185 (10)	102	10/10	180 (10)	99	10/10	172 (10)	95	10/10	154 (10)	85	10/10
3	209 (10)	10/10		213 (10)	102	10/10	212 (10)	101	10/10	207 (10)	99	10/10	198 (10)	95	10/10	176 (10)	84	10/10
4	232 (10)	10/10		235 (10)	101	10/10	234 (10)	101	10/10	228 (10)	98	10/10	219 (10)	94	10/10	193 (10)	83	10/10
5	250 (10)	10/10		253 (10)	101	10/10	251 (10)	100	10/10	245 (10)	98	10/10	238 (10)	95	10/10	208 (10)	83	10/10
6	264 (10)	10/10		269 (10)	102	10/10	266 (10)	101	10/10	258 (10)	98	10/10	252 (10)	95	10/10	219 (10)	83	10/10
7	278 (10)	10/10		283 (10)	102	10/10	281 (10)	101	10/10	272 (10)	98	10/10	263 (10)	95	10/10	231 (10)	83	10/10
8	290 (10)	10/10		296 (10)	102	10/10	294 (10)	101	10/10	283 (10)	98	10/10	275 (10)	95	10/10	237 (10)	82	10/10
9	303 (10)	10/10		310 (10)	102	10/10	308 (10)	102	10/10	296 (10)	98	10/10	286 (10)	94	10/10	247 (10)	82	10/10
10	312 (10)	10/10		318 (10)	102	10/10	315 (10)	101	10/10	303 (10)	97	10/10	295 (10)	95	10/10	256 (10)	82	10/10
11	321 (10)	10/10		325 (10)	101	10/10	325 (10)	101	10/10	313 (10)	98	10/10	304 (10)	95	10/10	263 (10)	82	10/10
12	328 (10)	10/10		332 (10)	101	10/10	333 (10)	102	10/10	319 (10)	97	10/10	309 (10)	94	10/10	268 (10)	82	10/10
13	333 (10)	10/10		338 (10)	102	10/10	337 (10)	101	10/10	324 (10)	97	10/10	314 (10)	94	10/10	270 (10)	81	10/10

< >:No. of effective animals, ():No. of measured animals Av. Wt. : g

(BI0040)

BATS 4

TABLE C 2

BODY WEIGHT CHANGES AND
SURVIVAL ANIMAL NUMBERS: FEMALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

MEAN BODY WEIGHTS AND SURVIVAL

PAGE : 2

Week on Study	Control			256 ppm			640 ppm			1600 ppm			4000 ppm			10000 ppm		
	Av. Wt.	No. of Surviv. <10>		Av. Wt.	% of cont. <10>	No. of Surviv.	Av. Wt.	% of cont. <10>	No. of Surviv.	Av. Wt.	% of cont. <10>	No. of Surviv.	Av. Wt.	% of cont. <10>	No. of Surviv.	Av. Wt.	% of cont. <10>	No. of Surviv.
0	97 (10)	10/10		97 (10)	100	10/10	97 (10)	100	10/10	97 (10)	100	10/10	97 (10)	100	10/10	97 (10)	100	10/10
1	113 (10)	10/10		112 (10)	99	10/10	113 (10)	100	10/10	110 (10)	97	10/10	109 (10)	96	10/10	101 (10)	89	10/10
2	126 (10)	10/10		124 (10)	98	10/10	125 (10)	99	10/10	123 (10)	98	10/10	121 (10)	96	10/10	113 (10)	90	10/10
3	137 (10)	10/10		134 (10)	98	10/10	137 (10)	100	10/10	132 (10)	96	10/10	130 (10)	95	10/10	121 (10)	88	10/10
4	145 (10)	10/10		142 (10)	98	10/10	143 (10)	99	10/10	139 (10)	96	10/10	137 (10)	94	10/10	128 (10)	88	10/10
5	155 (10)	10/10		149 (10)	96	10/10	150 (10)	97	10/10	147 (10)	95	10/10	142 (10)	92	10/10	133 (10)	86	10/10
6	159 (10)	10/10		155 (10)	97	10/10	156 (10)	98	10/10	152 (10)	96	10/10	146 (10)	92	10/10	138 (10)	87	10/10
7	164 (10)	10/10		159 (10)	97	10/10	161 (10)	98	10/10	155 (10)	95	10/10	150 (10)	91	10/10	141 (10)	86	10/10
8	170 (10)	10/10		162 (10)	95	10/10	164 (10)	96	10/10	157 (10)	92	10/10	152 (10)	89	10/10	145 (10)	85	10/10
9	174 (10)	10/10		165 (10)	95	10/10	168 (10)	97	10/10	162 (10)	93	10/10	157 (10)	90	10/10	147 (10)	84	10/10
10	178 (10)	10/10		170 (10)	96	10/10	172 (10)	97	10/10	165 (10)	93	10/10	159 (10)	89	10/10	150 (10)	84	10/10
11	181 (10)	10/10		172 (10)	95	10/10	175 (10)	97	10/10	169 (10)	93	10/10	164 (10)	91	10/10	155 (10)	86	10/10
12	183 (10)	10/10		174 (10)	95	10/10	178 (10)	97	10/10	172 (10)	94	10/10	167 (10)	91	10/10	157 (10)	86	10/10
13	187 (10)	10/10		177 (10)	95	10/10	180 (10)	96	10/10	173 (10)	93	10/10	169 (10)	90	10/10	159 (10)	85	10/10

< >:No. of effective animals, ():No. of measured animals

Av. Wt. : g

(BT0040)

BATS 4

TABLE C 3

BODY WEIGHT CHANGES: MALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration week		0		1		2		3		4		5		6	
Control	120±	3	149±	5	182±	6	209±	7	232±	8	250±	9	264±	9		
256 ppm	120±	3	150±	5	185±	6	213±	7	235±	8	253±	9	269±	12		
640 ppm	120±	3	151±	7	185±	10	212±	12	234±	13	251±	13	266±	14		
1600 ppm	120±	3	150±	5	180±	7	207±	8	228±	8	245±	9	258±	9		
4000 ppm	120±	3	143±	6*	172±	7*	198±	8*	219±	8**	238±	9*	252±	9*		
10000 ppm	120±	3	131±	3**	154±	5**	176±	6**	193±	7**	208±	8**	219±	9**		

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration		week											
	7		8		9		10		11		12		13	
Control	278±	8	290±	9	303±	10	312±	10	321±	12	328±	12	333±	12
256 ppm	283±	12	296±	14	310±	12	318±	15	325±	15	332±	14	338±	15
640 ppm	281±	14	294±	14	308±	14	315±	13	325±	14	333±	15	337±	16
1600 ppm	272±	10	283±	11	296±	13	303±	13	313±	14	319±	13	324±	12
4000 ppm	263±	10*	275±	10*	286±	11*	295±	10**	304±	10*	309±	9**	314±	11**
10000 ppm	231±	9**	237±	9**	247±	9**	256±	9**	263±	9**	268±	11**	270±	11**

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 4

TABLE C 4

BODY WEIGHT CHANGES: FEMALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week		1		2		3		4		5		6	
	0													
Control	97±	3	113±	4	126±	4	137±	6	145±	7	155±	7	159±	8
256 ppm	97±	3	112±	5	124±	6	134±	5	142±	7	149±	7	155±	8
640 ppm	97±	3	113±	3	125±	4	137±	5	143±	5	150±	5	156±	5
1600 ppm	97±	3	110±	5	123±	6	132±	7	139±	8	147±	7*	152±	9
4000 ppm	97±	3	109±	3	121±	4	130±	5*	137±	6*	142±	6**	146±	6**
10000 ppm	97±	3	101±	3**	113±	4**	121±	6**	128±	6**	133±	6**	138±	7**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week		7		8		9		10		11		12		13	
Control	164±	8	170±	9	174±	11	178±	11	181±	10	183±	9	187±	10		
256 ppm	159±	9	162±	9	165±	9	170±	9	172±	11	174±	9	177±	9		
640 ppm	161±	5	164±	6	168±	6	172±	5	175±	5	178±	7	180±	6		
1600 ppm	155±	10	157±	10**	162±	11*	165±	9**	169±	10*	172±	10*	173±	11**		
4000 ppm	150±	7**	152±	7**	157±	9**	159±	8**	164±	8**	167±	7**	169±	9**		
10000 ppm	141±	8**	145±	7**	147±	7**	150±	7**	155±	9**	157±	8**	159±	8**		

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 4

TABLE D 1

FOOD CONSUMPTION CHANGES AND
SURVIVAL ANIMAL NUMBERS: MALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

MEAN FOOD CONSUMPTION(FC) AND SURVIVAL

PAGE : 1

Week on Study	Control		256 ppm			640 ppm			1600 ppm			4000 ppm			10000 ppm		
	Av.FC.	No.of Surviv. <10>	Av.FC.	% of cont. <10>	No.of Surviv.	Av.FC.	% of cont. <10>	No.of Surviv.	Av.FC.	% of cont. <10>	No.of Surviv.	Av.FC.	% of cont. <10>	No.of Surviv.	Av.FC.	% of cont. <10>	No.of Surviv.
1	13.2 (10)	10/10	13.2 (10)	100	10/10	13.2 (10)	100	10/10	12.7 (10)	96	10/10	11.4 (10)	86	10/10	9.1 (10)	69	10/10
2	14.0 (10)	10/10	14.5 (10)	104	10/10	14.4 (10)	103	10/10	13.7 (10)	98	10/10	12.9 (10)	92	10/10	11.5 (10)	82	10/10
3	14.9 (10)	10/10	15.3 (10)	103	10/10	15.1 (10)	101	10/10	14.6 (10)	98	10/10	13.9 (10)	93	10/10	12.0 (10)	81	10/10
4	15.1 (10)	10/10	15.2 (10)	101	10/10	15.1 (10)	100	10/10	14.6 (10)	97	10/10	14.2 (10)	94	10/10	11.9 (9)	79	10/10
5	15.2 (10)	10/10	15.6 (10)	103	10/10	15.4 (10)	101	10/10	14.8 (10)	97	10/10	14.6 (10)	96	10/10	12.2 (10)	80	10/10
6	15.1 (10)	10/10	15.6 (10)	103	10/10	15.3 (10)	101	10/10	14.4 (10)	95	10/10	14.5 (10)	96	10/10	12.2 (10)	81	10/10
7	15.3 (10)	10/10	15.9 (10)	104	10/10	15.5 (10)	101	10/10	14.8 (10)	97	10/10	14.3 (10)	93	10/10	12.2 (10)	80	10/10
8	15.2 (10)	10/10	15.8 (10)	104	10/10	15.3 (10)	101	10/10	14.6 (10)	96	10/10	14.3 (10)	94	10/10	12.1 (10)	80	10/10
9	15.3 (10)	10/10	15.8 (10)	103	10/10	15.5 (10)	101	10/10	14.8 (10)	97	10/10	14.1 (10)	92	10/10	12.2 (10)	80	10/10
10	15.4 (10)	10/10	15.7 (10)	102	10/10	15.5 (10)	101	10/10	14.6 (10)	95	10/10	14.3 (9)	93	10/10	12.4 (10)	81	10/10
11	15.4 (10)	10/10	15.6 (10)	101	10/10	15.5 (10)	101	10/10	14.7 (10)	95	10/10	14.3 (10)	93	10/10	12.3 (10)	80	10/10
12	15.3 (10)	10/10	15.4 (10)	101	10/10	15.4 (10)	101	10/10	14.5 (10)	95	10/10	14.3 (9)	93	10/10	12.5 (10)	82	10/10
13	15.1 (10)	10/10	15.2 (10)	101	10/10	15.3 (10)	101	10/10	14.4 (10)	95	10/10	14.3 (10)	95	10/10	12.2 (10)	81	10/10
< >:No. of effective animals, ():No. of measured animals Av.FC. : g																	

(BI0040)

BAIS 4

TABLE D 2

FOOD CONSUMPTION CHANGES AND
SURVIVAL ANIMAL NUMBERS: FEMALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

MEAN FOOD CONSUMPTION(FC) AND SURVIVAL

PAGE : 2

Week on Study	Control		256 ppm			640 ppm			1600 ppm			4000 ppm			10000 ppm		
	Av. FC.	No. of Surviv. <10>	Av. FC.	% of cont. <10>	No. of Surviv.	Av. FC.	% of cont. <10>	No. of Surviv.	Av. FC.	% of cont. <10>	No. of Surviv.	Av. FC.	% of cont. <10>	No. of Surviv.	Av. FC.	% of cont. <10>	No. of Surviv.
1	10.3 (10)	10/10	10.2 (10)	99	10/10	10.3 (10)	100	10/10	9.6 (10)	93	10/10	9.1 (10)	88	10/10	7.5 (10)	73	10/10
2	10.5 (10)	10/10	10.4 (10)	99	10/10	10.5 (10)	100	10/10	10.2 (10)	97	10/10	9.8 (10)	93	10/10	8.8 (10)	84	10/10
3	10.8 (10)	10/10	10.5 (10)	97	10/10	10.6 (10)	98	10/10	10.2 (10)	94	10/10	9.6 (10)	89	10/10	8.5 (10)	79	10/10
4	11.0 (10)	10/10	10.5 (10)	95	10/10	10.6 (10)	96	10/10	10.2 (10)	93	10/10	9.4 (10)	85	10/10	8.1 (10)	74	10/10
5	11.1 (10)	10/10	10.6 (10)	95	10/10	10.5 (10)	95	10/10	10.4 (10)	94	10/10	9.5 (10)	86	10/10	8.3 (10)	75	10/10
6	10.9 (10)	10/10	10.6 (10)	97	10/10	10.4 (10)	95	10/10	9.8 (10)	90	10/10	9.3 (10)	85	10/10	8.2 (10)	75	10/10
7	11.2 (10)	10/10	10.6 (10)	95	10/10	10.3 (10)	92	10/10	10.0 (10)	89	10/10	9.5 (10)	85	10/10	8.2 (10)	73	10/10
8	10.9 (10)	10/10	10.1 (10)	93	10/10	10.2 (10)	94	10/10	9.6 (10)	88	10/10	9.3 (10)	85	10/10	8.1 (10)	74	10/10
9	10.7 (10)	10/10	10.1 (10)	94	10/10	10.2 (10)	95	10/10	9.6 (10)	90	10/10	9.3 (10)	87	10/10	8.2 (10)	77	10/10
10	10.2 (10)	10/10	10.0 (10)	98	10/10	10.0 (10)	98	10/10	9.6 (10)	94	10/10	9.0 (10)	88	10/10	8.2 (10)	80	10/10
11	10.4 (10)	10/10	10.0 (10)	96	10/10	10.1 (10)	97	10/10	9.8 (10)	94	10/10	9.1 (10)	88	10/10	8.1 (10)	78	10/10
12	10.4 (10)	10/10	9.8 (10)	94	10/10	10.2 (10)	98	10/10	9.7 (10)	93	10/10	9.2 (10)	88	10/10	8.1 (10)	78	10/10
13	10.3 (10)	10/10	9.9 (10)	96	10/10	10.0 (10)	97	10/10	9.6 (10)	93	10/10	9.3 (10)	90	10/10	8.3 (10)	81	10/10
< >:No. of effective animals, ():No. of measured animals																	
Av. FC. : g																	

(BI0040)

BAIS 4

TABLE D 3

FOOD CONSUMPTION CHANGES: MALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration week						
	1	2	3	4	5	6	7
Control	13.2± 0.4	14.0± 0.7	14.9± 0.8	15.1± 0.8	15.2± 0.6	15.1± 0.6	15.3± 0.6
256 ppm	13.2± 0.7	14.5± 0.6	15.3± 0.6	15.2± 0.7	15.6± 0.6	15.6± 0.7	15.9± 0.8
640 ppm	13.2± 0.5	14.4± 0.8	15.1± 1.3	15.1± 1.2	15.4± 0.8	15.3± 0.5	15.5± 0.6
1600 ppm	12.7± 0.5	13.7± 0.5	14.6± 0.7	14.6± 0.6	14.8± 0.8	14.4± 0.7*	14.8± 0.8
4000 ppm	11.4± 0.5**	12.9± 0.7**	13.9± 0.7*	14.2± 0.8	14.6± 0.5	14.5± 0.7	14.3± 0.9*
10000 ppm	9.1± 0.4**	11.5± 0.4**	12.0± 0.6**	11.9± 0.7**	12.2± 0.7**	12.2± 0.7**	12.2± 0.5**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration week					
	8	9	10	11	12	13
Control	15.2± 0.7	15.3± 0.8	15.4± 0.8	15.4± 0.8	15.3± 0.9	15.1± 0.8
256 ppm	15.8± 1.0	15.8± 0.5	15.7± 0.7	15.6± 0.7	15.4± 0.6	15.2± 0.7
640 ppm	15.3± 0.9	15.5± 0.9	15.5± 0.7	15.5± 1.0	15.4± 1.1	15.3± 1.2
1600 ppm	14.6± 0.8	14.8± 0.9	14.6± 0.9	14.7± 1.0	14.5± 0.9	14.4± 0.9
4000 ppm	14.3± 0.8	14.1± 0.7**	14.3± 0.6**	14.3± 0.7*	14.3± 0.7*	14.3± 1.2
10000 ppm	12.1± 0.5**	12.2± 0.4**	12.4± 0.7**	12.3± 0.5**	12.5± 0.5**	12.2± 0.4**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 4

TABLE D 4

FOOD CONSUMPTION CHANGES: FEMALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration week						
	1	2	3	4	5	6	7
Control	10.3± 0.5	10.5± 0.5	10.8± 0.8	11.0± 0.8	11.1± 0.9	10.9± 0.6	11.2± 0.9
256 ppm	10.2± 0.5	10.4± 0.4	10.5± 0.6	10.5± 0.7	10.6± 0.6	10.6± 0.7	10.6± 0.8
640 ppm	10.3± 0.6	10.5± 0.4	10.6± 0.5	10.6± 0.6	10.5± 0.4	10.4± 0.7	10.3± 0.7
1600 ppm	9.6± 0.4**	10.2± 0.3	10.2± 0.5	10.2± 0.6	10.4± 0.7	9.8± 0.8**	10.0± 0.7**
4000 ppm	9.1± 0.4**	9.8± 0.6**	9.6± 0.4**	9.4± 0.5**	9.5± 0.6**	9.3± 0.4**	9.5± 0.4**
10000 ppm	7.5± 0.4**	8.8± 0.3**	8.5± 0.7**	8.1± 0.8**	8.3± 0.7**	8.2± 0.8**	8.2± 0.7**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 4

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration week					
	8	9	10	11	12	13
Control	10.9± 1.0	10.7± 0.8	10.2± 0.7	10.4± 0.6	10.4± 0.6	10.3± 0.8
256 ppm	10.1± 0.8	10.1± 0.9	10.0± 0.8	10.0± 0.8	9.8± 0.6*	9.9± 0.6
640 ppm	10.2± 0.5	10.2± 0.5	10.0± 0.4	10.1± 0.4	10.2± 0.5	10.0± 0.5
1600 ppm	9.6± 0.7**	9.6± 0.8**	9.6± 0.5	9.8± 0.8	9.7± 0.6*	9.6± 0.6*
4000 ppm	9.3± 0.6**	9.3± 0.5**	9.0± 0.6**	9.1± 0.5**	9.2± 0.5**	9.3± 0.7**
10000 ppm	8.1± 0.6**	8.2± 0.7**	8.2± 0.6**	8.1± 0.7**	8.1± 0.5**	8.3± 0.6**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HAN260)

BAIS 4

TABLE E 1

CHEMICAL INTAKE CHANGES: MALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : mg/kg/day
 REPORT TYPE : A1 13
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 1

Group Name	Administration (weeks)													
	1	2	3	4	5	6	7							
Control	0± 0	0± 0	0± 0	0± 0	0± 0	0± 0	0± 0							
256 ppm	22± 1	20± 1	19± 1	17± 1	16± 0	15± 0	14± 1							
640 ppm	56± 2	50± 1	45± 2	42± 2	39± 1	37± 2	36± 1							
1600 ppm	136± 4	122± 3	113± 3	103± 3	96± 3	89± 2	87± 3							
4000 ppm	319± 7	300± 8	280± 9	259± 9	245± 8	230± 9	218± 8							
10000 ppm	695± 24	749± 16	682± 18	613± 21	585± 22	555± 27	530± 17							

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : mg/kg/day
 REPORT TYPE : A1 13
 SEX : MALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 2

Group Name	Administration (weeks)											
	8		9		10		11		12		13	
Control	0±	0	0±	0	0±	0	0±	0	0±	0	0±	0
256 ppm	14±	1	13±	0	13±	1	12±	0	12±	0	12±	1
640 ppm	33±	1	32±	1	32±	1	31±	1	30±	1	29±	2
1600 ppm	83±	2	80±	2	77±	2	75±	2	73±	2	71±	2
4000 ppm	208±	7	197±	9	194±	8	188±	7	186±	10	182±	13
10000 ppm	511±	19	492±	14	486±	26	466±	19	466±	17	452±	15

TABLE E 2

CHEMICAL INTAKE CHANGES: FEMALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : mg/kg/day
 REPORT TYPE : A1 13
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

Group Name	Administration (weeks)													
	1		2		3		4		5		6		7	
Control	0±	0	0±	0	0±	0	0±	0	0±	0	0±	0	0±	0
256 ppm	23±	1	22±	1	20±	1	19±	1	18±	1	17±	1	17±	1
640 ppm	59±	2	54±	1	50±	1	47±	1	45±	2	43±	2	41±	2
1600 ppm	140±	3	132±	3	123±	5	117±	4	113±	5	103±	4	103±	5
4000 ppm	332±	11	323±	11	294±	7	274±	9	266±	12	254±	10	255±	9
10000 ppm	741±	38	786±	27	703±	30	634±	41	621±	32	590±	38	582±	28

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : mg/kg/day
 REPORT TYPE : A1 13
 SEX : FEMALE

CHEMICAL INTAKE CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 4

Group Name	Administration (weeks)											
	8		9		10		11		12		13	
Control	0±	0	0±	0	0±	0	0±	0	0±	0	0±	0
256 ppm	16±	1	16±	1	15±	1	15±	1	14±	1	15±	1
640 ppm	40±	1	39±	1	37±	1	37±	1	37±	1	36±	1
1600 ppm	98±	5	95±	4	93±	3	93±	6	91±	4	89±	4
4000 ppm	245±	11	237±	9	227±	13	222±	11	222±	8	220±	12
10000 ppm	557±	26	556±	24	543±	26	524±	25	517±	14	519±	21

(IAN300)

BAIS 4

TABLE F 1

HEMATOLOGY: MALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : MALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 ³ /μl	
Control	10	9.18±	0.21	16.0±	0.3	42.7±	1.0	46.5±	0.5	17.5±	0.2	37.5±	0.1	765±	39
256 ppm	10	9.23±	0.18	16.1±	0.3	43.0±	0.8	46.5±	0.3	17.5±	0.2	37.5±	0.4	778±	33
640 ppm	10	9.12±	0.20	15.9±	0.4	42.4±	0.9	46.4±	0.3	17.5±	0.2	37.7±	0.3	793±	33
1600 ppm	10	9.06±	0.09	15.9±	0.2	42.2±	0.5	46.6±	0.4	17.6±	0.2	37.7±	0.4	797±	40
4000 ppm	10	9.15±	0.18	16.1±	0.4	42.7±	0.8	46.7±	0.4	17.6±	0.2	37.7±	0.6	780±	60
10000 ppm	10	9.12±	0.16	16.2±	0.3	43.0±	0.8	47.1±	0.4**	17.8±	0.2**	37.8±	0.2	805±	59

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0719
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
MEASURE. TIME : 1
SEX : MALE

HEMATOLOGY (SUMMARY)
ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	RETICULOCYTE %		METHEMOGLOBIN %	
Control	10	1.6±	0.1	0.7±	0.1
256 ppm	10	1.7±	0.1	0.7±	0.2
640 ppm	10	1.7±	0.1	0.7±	0.1
1600 ppm	10	1.7±	0.2	0.6±	0.1
4000 ppm	10	1.6±	0.2	0.7±	0.1
10000 ppm	10	1.5±	0.3	0.8±	0.1

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : MALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	WBC 1 O ³ /μl		Differential		WBC (%)		MONO		EOSINO		BASO		OTHER	
				NEUTRO		LYMPHO									
Control	10	6.33±	1.41	25±	6	71±	6	2±	0	1±	0	0±	0	1±	0
256 ppm	10	6.93±	1.14	21±	3	74±	3	2±	1	1±	1	0±	1	1±	0
640 ppm	10	6.32±	1.50	22±	4	72±	5	3±	1	1±	0	0±	1	1±	0
1600 ppm	10	6.57±	1.52	21±	2	74±	3	3±	1	1±	0	0±	0	1±	1
4000 ppm	10	6.31±	2.11	22±	4	74±	4	2±	0	1±	0	0±	0	1±	1
10000 ppm	10	5.85±	1.33	19±	3	77±	4	2±	0	1±	0	0±	0	1±	0

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAS 4

TABLE F 2

HEMATOLOGY: FEMALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : FEMALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 ³ /μl	
Control	10	8.53±	0.25	16.0±	0.5	41.5±	1.2	48.6±	0.3	18.8±	0.2	38.5±	0.3	863±	66
256 ppm	10	8.63±	0.25	16.2±	0.5	42.0±	1.3	48.7±	0.4	18.8±	0.1	38.6±	0.3	827±	40
640 ppm	10	8.58±	0.14	16.1±	0.3	41.8±	0.7	48.8±	0.5	18.8±	0.1	38.5±	0.4	827±	87
1600 ppm	10	8.59±	0.27	16.2±	0.5	42.1±	1.2	49.1±	0.5	18.8±	0.1	38.4±	0.4	836±	66
4000 ppm	10	8.52±	0.23	16.0±	0.4	41.6±	1.0	48.8±	0.3	18.8±	0.2	38.6±	0.3	832±	53
10000 ppm	10	8.51±	0.27	16.0±	0.5	41.4±	1.4	48.7±	0.3	18.8±	0.1	38.6±	0.3	858±	33

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0719
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
MEASURE. TIME : 1
SEX : FEMALE

HEMATOLOGY (SUMMARY)
ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 5

Group Name	NO. of Animals	RETICULOCYTE %		METHEMOGLOBIN %	
Control	10	1.5±	0.2	0.7±	0.1
256 ppm	10	1.4±	0.2	0.7±	0.1
640 ppm	10	1.4±	0.2	0.7±	0.1
1600 ppm	10	1.5±	0.2	0.7±	0.1
4000 ppm	10	1.6±	0.2	0.8±	0.1
10000 ppm	10	1.6±	0.2	0.8±	0.1

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : FEMALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 6

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential NEUTRO		WBC (%) LYMPHO		MONO		EOSINO		BASO		OTHER	
Control	10	3.52±	0.94	24±	4	71±	4	3±	1	2±	1	0±	0	1±	0
256 ppm	10	3.92±	1.21	22±	4	73±	3	2±	1	1±	0	0±	0	1±	0
640 ppm	10	3.07±	1.02	23±	4	72±	5	2±	1	2±	1	0±	0	1±	1
1600 ppm	10	2.97±	1.13	21±	5	74±	6	3±	1	2±	1	0±	0	1±	0
4000 ppm	10	3.16±	1.41	26±	5	69±	5	2±	1	1±	0	0±	0	1±	0
10000 ppm	10	3.86±	1.42	21±	6	76±	6	2±	1	1±	0	0±	0	1±	0

Significant difference : * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 4

TABLE G 1

BIOCHEMISTRY: MALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	10	6.6±	0.2	3.5±	0.1	1.1±	0.1	0.10±	0.01	177±	8	64±	6	53±	19
256 ppm	10	6.7±	0.1	3.6±	0.1	1.1±	0.1	0.11±	0.01	183±	6	67±	5	58±	19
640 ppm	10	6.7±	0.2	3.5±	0.1	1.1±	0.1	0.10±	0.01	181±	10	68±	4	51±	18
1600 ppm	10	6.7±	0.1	3.5±	0.0	1.1±	0.1	0.10±	0.01	183±	8	72±	8**	51±	17
4000 ppm	10	6.7±	0.1	3.6±	0.1	1.2±	0.1	0.10±	0.00	187±	15	71±	4*	37±	14
10000 ppm	10	6.7±	0.2	3.7±	0.1**	1.2±	0.1**	0.11±	0.01	178±	9	82±	5**	29±	10**

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		AST I U / ℓ		ALT I U / ℓ		LDH I U / ℓ		ALP I U / ℓ		G-GTP I U / ℓ		CK I U / ℓ	
Control	10	113±	7	81±	16	43±	6	92±	35	386±	27	1±	0	95±	18
256 ppm	10	119±	8	94±	21	47±	6	104±	31	380±	28	1±	1	91±	11
640 ppm	10	118±	7	80±	14	43±	5	103±	36	394±	26	1±	0	96±	17
1600 ppm	10	125±	13**	80±	11	41±	3	99±	27	372±	25	1±	0	92±	14
4000 ppm	10	124±	5*	77±	18	38±	6	112±	31	383±	34	1±	1	97±	10
10000 ppm	10	140±	8**	69±	11	36±	5*	104±	28	362±	32	2±	0	92±	12

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : MALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	UREA NITROGEN mg/dl		CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	10	19.0±	1.1	0.6±	0.1	141±	1	3.4±	0.2	104±	2	10.4±	0.3	5.7±	0.6
256 ppm	10	19.0±	1.3	0.5±	0.0	141±	1	3.3±	0.2	104±	1	10.4±	0.3	5.7±	0.6
640 ppm	10	19.3±	1.6	0.6±	0.1	141±	1	3.3±	0.2	103±	1	10.5±	0.1	5.5±	0.5
1600 ppm	10	19.2±	1.7	0.6±	0.1	140±	1	3.4±	0.3	103±	1	10.5±	0.2	5.7±	0.6
4000 ppm	10	21.2±	1.6*	0.6±	0.1	140±	1	3.4±	0.2	103±	1	10.4±	0.2	5.5±	0.7
10000 ppm	10	21.3±	1.9**	0.5±	0.0	140±	1	3.5±	0.2	103±	1	10.4±	0.1	5.6±	0.4

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 4

TABLE G 2

BIOCHEMISTRY: FEMALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	10	6.5±	0.2	3.5±	0.1	1.2±	0.1	0.11±	0.01	141±	20	75±	6	11±	5
256 ppm	10	6.5±	0.3	3.5±	0.1	1.2±	0.1	0.12±	0.01	144±	19	76±	8	11±	2
640 ppm	10	6.5±	0.2	3.6±	0.1	1.2±	0.1	0.11±	0.01	142±	14	76±	6	13±	3
1600 ppm	10	6.5±	0.2	3.6±	0.1	1.2±	0.1	0.11±	0.01	142±	16	74±	5	11±	4
4000 ppm	10	6.4±	0.1	3.5±	0.1	1.2±	0.1	0.11±	0.01	148±	11	75±	4	12±	4
10000 ppm	10	6.3±	0.2*	3.4±	0.1	1.2±	0.0	0.11±	0.01	155±	12	82±	6	14±	4

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 5

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		AST IU/l		ALT IU/l		LDH IU/l		ALP IU/l		G-GTP IU/l		CK IU/l	
Control	10	138±	10	76±	12	40±	14	103±	36	296±	27	2±	1	100±	19
256 ppm	10	141±	12	75±	12	36±	6	105±	48	286±	24	1±	1	105±	31
640 ppm	10	140±	10	76±	13	39±	8	90±	29	268±	37	2±	0	93±	16
1600 ppm	10	135±	10	73±	11	36±	8	95±	39	294±	23	2±	1	98±	21
4000 ppm	10	138±	8	73±	7	32±	4	93±	23	304±	34	2±	1	89±	13
10000 ppm	10	145±	10	67±	5	36±	5	87±	18	376±	61**	5±	1**	84±	12

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 6

Group Name	NO. of Animals	UREA NITROGEN mg/dl		CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	10	17.7±	1.1	0.6±	0.0	142±	1	3.1±	0.3	106±	2	10.1±	0.2	4.9±	1.2
256 ppm	10	17.7±	1.5	0.6±	0.1	141±	1	3.1±	0.2	105±	1	10.1±	0.1	5.0±	1.2
640 ppm	10	17.8±	2.0	0.6±	0.0	141±	1	3.2±	0.4	105±	2	10.0±	0.2	4.8±	1.3
1600 ppm	10	18.1±	1.4	0.6±	0.1	142±	1	3.1±	0.3	106±	2	10.0±	0.2	4.8±	1.1
4000 ppm	10	19.8±	1.7*	0.6±	0.1	141±	1	3.2±	0.2	106±	2	9.9±	0.1	4.9±	1.1
10000 ppm	10	22.0±	2.5**	0.5±	0.0	141±	1	3.6±	0.2**	106±	1	9.9±	0.2	5.5±	0.8

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 4

TABLE H 1

URINALYSIS: MALE

STUDY NO. : 0719

URINALYSIS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	pH							CHI	Protein					CHI	Glucose					CHI	Ketone body					CHI	Bilirubin				CHI		
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		—	±	+	2+	3+		4+	—	±	+	2+		3+	4+	—	±	+		2+	3+	4+	—		+	2+
Control	10	0	0	0	0	0	4	6		0	0	0	8	2	0		10	0	0	0	0	0		3	3	4	0	0	0		10	0	0	0
256 ppm	10	0	0	0	0	0	4	6		0	0	1	8	1	0		10	0	0	0	0	0		4	2	4	0	0	0		10	0	0	0
640 ppm	10	0	0	0	0	0	2	8		0	0	2	7	1	0		10	0	0	0	0	0		3	2	5	0	0	0		10	0	0	0
1600 ppm	10	0	0	0	0	0	4	6		0	0	2	7	1	0		10	0	0	0	0	0		4	2	4	0	0	0		10	0	0	0
4000 ppm	10	0	0	0	0	0	5	5		0	0	4	3	3	0	*	10	0	0	0	0	0		3	2	5	0	0	0		10	0	0	0
10000 ppm	10	0	0	0	1	6	3	0	**	0	0	3	7	0	0		10	0	0	0	0	0		6	2	2	0	0	0		10	0	0	0

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of CHI SQUARE

(HCL101)

BATS 4

STUDY NO. : 0719

URINALYSIS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		-	±	+	2+	3+		±	+	2+	3+	4+	
Control	10	10	0	0	0	0	0	10	0	0	0	0	0
256 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
640 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
1600 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
4000 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
10000 ppm	10	10	0	0	0	0	0	10	0	0	0	0	0

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of CHI SQUARE

(HCL101)

BATS4

TABLE H 2

URINALYSIS: FEMALE

STUDY NO. : 0719

URINALYSIS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	pH							CHI	Protein						CHI	Glucose						CHI	Ketone body						CHI	Bilirubin					CHI
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+	4+		-	±	+	2+	3+	4+		-	±	+	2+	3+	4+		-	+	2+	3+	4+	
Control	10	0	0	0	1	0	6	3		0	2	6	2	0	0		10	0	0	0	0	0		5	5	0	0	0	0		10	0	0	0		
256 ppm	10	0	0	0	0	0	7	3		0	1	6	3	0	0		10	0	0	0	0	0		5	5	0	0	0	0		10	0	0	0		
640 ppm	10	0	0	0	0	1	8	1		0	2	7	1	0	0		10	0	0	0	0	0		3	7	0	0	0	0		10	0	0	0		
1600 ppm	10	0	0	0	0	1	6	3		0	1	9	0	0	0		10	0	0	0	0	0		4	6	0	0	0	0		10	0	0	0		
4000 ppm	10	0	0	1	0	0	5	4		0	2	8	0	0	0		10	0	0	0	0	0		1	9	0	0	0	0		10	0	0	0		
10000 ppm	10	0	0	0	2	3	5	0		0	0	4	6	0	0		10	0	0	0	0	0		0	10	0	0	0	0	**	10	0	0	0		

Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of CHI SQUARE

(HCL101)

BAIS 4

STUDY NO. : 0719

URINALYSIS

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE TIME : 1

SEX : FEMALE

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		—	±	+	2+	3+		±	+	2+	3+	4+	
Control	10	10	0	0	0	0		10	0	0	0	0	
256 ppm	10	10	0	0	0	0		10	0	0	0	0	
640 ppm	10	10	0	0	0	0		10	0	0	0	0	
1600 ppm	10	10	0	0	0	0		10	0	0	0	0	
4000 ppm	10	10	0	0	0	0		10	0	0	0	0	
10000 ppm	10	10	0	0	0	0		10	0	0	0	0	

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of CHI SQUARE

(HCL101)

BATS 4

TABLE I 1

GROSS FINDINGS: MALE: ALL ANIMALS

STUDY NO. : 0719
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 1

Organ	Findings	Group Name	Control	256 ppm	640 ppm	1600 ppm
		NO. of Animals	10 (%)	10 (%)	10 (%)	10 (%)
thymus	red zone		0 (0)	0 (0)	0 (0)	1 (10)
forestomach	thick		0 (0)	0 (0)	0 (0)	0 (0)
liver	herniation		1 (10)	1 (10)	0 (0)	1 (10)

(HPT080)

BAIS 4

STUDY NO. : 0719
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 2

Organ	Findings	Group Name	4000 ppm	10000 ppm
		NO. of Animals	10 (%)	10 (%)
thymus	red zone		0 (0)	0 (0)
forestomach	thick		0 (0)	9 (90)
liver	herniation		0 (0)	1 (10)

(HPT080)

BAIS 4

TABLE I 2

GROSS FINDINGS: FEMALE: ALL ANIMALS

STUDY NO. : 0719
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control	256 ppm	640 ppm	1600 ppm
			10 (%)	10 (%)	10 (%)	10 (%)
forestomach	thick		0 (0)	0 (0)	0 (0)	0 (0)
liver	herniation		3 (30)	2 (20)	1 (10)	0 (0)
ovary	cyst		0 (0)	0 (0)	0 (0)	0 (0)

(HPT080)

BAIS 4

STUDY NO. : 0719
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : AI
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 4

Organ	Findings	Group Name	4000 ppm	10000 ppm
		NO. of Animals	10 (%)	10 (%)
forestomach	thick		0 (0)	10 (100)
liver	herniation		0 (0)	0 (0)
ovary	cyst		0 (0)	1 (10)

(HPT080)

BAIS 4

TABLE J 1

ORGAN WEIGHT, ABSOLUTE: MALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (14W)

PAGE : 1

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	313± 13	0.222± 0.020	0.049± 0.005	3.198± 0.075	0.964± 0.106	0.997± 0.049
256 ppm	10	317± 14	0.251± 0.036	0.048± 0.003	3.165± 0.283	0.986± 0.032	1.003± 0.031
640 ppm	10	318± 16	0.256± 0.031*	0.052± 0.008	3.230± 0.080	0.960± 0.056	1.025± 0.038
1600 ppm	10	304± 12	0.242± 0.022	0.049± 0.005	3.258± 0.091	0.950± 0.056	0.976± 0.049
4000 ppm	10	293± 11**	0.210± 0.018	0.047± 0.003	3.293± 0.058	0.931± 0.062	0.982± 0.045
10000 ppm	10	253± 11**	0.178± 0.016**	0.042± 0.003**	3.198± 0.073	0.780± 0.029**	0.867± 0.044**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL040)

BAIS 4

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (14W)

PAGE : 2

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	1.893±	0.093	0.602±	0.033	7.428±	0.443	1.901±	0.051
256 ppm	10	1.965±	0.111	0.607±	0.024	7.808±	0.375	1.934±	0.040
640 ppm	10	2.003±	0.083	0.617±	0.031	7.833±	0.419	1.937±	0.048
1600 ppm	10	1.934±	0.085	0.582±	0.032	7.609±	0.476	1.928±	0.054
4000 ppm	10	1.948±	0.123	0.565±	0.028*	7.613±	0.569	1.917±	0.033
10000 ppm	10	1.729±	0.082**	0.503±	0.022**	6.850±	0.370*	1.866±	0.048
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett									

(HCL040)

BAIS 4

TABLE J 2

ORGAN WEIGHT, ABSOLUTE: FEMALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (14W)

PAGE : 3

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	172± 10	0.212± 0.028	0.054± 0.005	0.106± 0.016	0.616± 0.036	0.731± 0.043
256 ppm	10	164± 8	0.182± 0.029*	0.054± 0.006	0.105± 0.016	0.614± 0.025	0.687± 0.039
640 ppm	10	167± 6	0.182± 0.022*	0.054± 0.006	0.108± 0.014	0.626± 0.037	0.708± 0.036
1600 ppm	10	160± 10*	0.179± 0.019**	0.050± 0.005	0.108± 0.019	0.601± 0.037	0.688± 0.044
4000 ppm	10	154± 7**	0.174± 0.018**	0.050± 0.006	0.104± 0.010	0.582± 0.029	0.677± 0.029*
10000 ppm	10	148± 8**	0.173± 0.020**	0.045± 0.004**	0.089± 0.021	0.546± 0.044**	0.641± 0.038**
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett							

(HCL040)

BAIS 4

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)
 SURVIVAL ANIMALS (14W)

PAGE : 4

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
Control	10	1.144±	0.052	0.402±	0.027	4.028±	0.240	1.762±	0.025
256 ppm	10	1.138±	0.037	0.370±	0.016*	3.847±	0.220	1.757±	0.043
640 ppm	10	1.133±	0.039	0.375±	0.015	3.916±	0.113	1.774±	0.037
1600 ppm	10	1.095±	0.054	0.368±	0.026**	3.786±	0.262	1.750±	0.047
4000 ppm	10	1.103±	0.053	0.351±	0.020**	3.794±	0.236	1.755±	0.044
10000 ppm	10	1.069±	0.050**	0.344±	0.034**	3.871±	0.222	1.726±	0.039
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett									

(HCL040)

BAIS 4

TABLE K 1

ORGAN WEIGHT, RELATIVE: MALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE
 UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
 SURVIVAL ANIMALS (14W)

PAGE : 1

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	313± 13	0.071± 0.007	0.016± 0.002	1.024± 0.044	0.308± 0.024	0.319± 0.012
256 ppm	10	317± 14	0.079± 0.011	0.015± 0.000	1.001± 0.106	0.311± 0.011	0.317± 0.010
640 ppm	10	318± 16	0.080± 0.009*	0.016± 0.003	1.018± 0.052	0.302± 0.014	0.323± 0.013
1600 ppm	10	304± 12	0.080± 0.008	0.016± 0.002	1.072± 0.045	0.312± 0.016	0.321± 0.017
4000 ppm	10	293± 11**	0.072± 0.006	0.016± 0.001	1.123± 0.034**	0.317± 0.016	0.335± 0.012*
10000 ppm	10	253± 11**	0.070± 0.005	0.017± 0.001	1.265± 0.050**	0.309± 0.016	0.343± 0.014**

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$

Test of Dunnett

(HCL042)

BAIS 4

STUDY NO. : 0719
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (14W)

PAGE : 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.605± 0.019	0.193± 0.005	2.375± 0.090	0.608± 0.022
256 ppm	10	0.620± 0.024	0.192± 0.005	2.463± 0.063	0.611± 0.036
640 ppm	10	0.630± 0.014*	0.194± 0.008	2.464± 0.082	0.610± 0.033
1600 ppm	10	0.636± 0.024**	0.191± 0.008	2.498± 0.071**	0.634± 0.031
4000 ppm	10	0.664± 0.028**	0.193± 0.008	2.592± 0.112**	0.654± 0.017**
10000 ppm	10	0.683± 0.013**	0.199± 0.007	2.706± 0.076**	0.738± 0.025**
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett					

(HCL042)

BAIS 4

TABLE K 2

ORGAN WEIGHT, RELATIVE: FEMALE

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE
 UNIT: %

ORGAN WEIGHT-RELATIVE (SUMMARY)
 SURVIVAL ANIMALS (14W)

PAGE : 3

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	172± 10	0.123± 0.012	0.032± 0.003	0.062± 0.009	0.359± 0.020	0.425± 0.025
256 ppm	10	164± 8	0.111± 0.015	0.033± 0.004	0.064± 0.009	0.375± 0.015	0.420± 0.013
640 ppm	10	167± 6	0.109± 0.010	0.032± 0.004	0.065± 0.008	0.375± 0.014	0.424± 0.015
1600 ppm	10	160± 10*	0.111± 0.008	0.031± 0.003	0.068± 0.012	0.375± 0.023	0.430± 0.031
4000 ppm	10	154± 7**	0.113± 0.010	0.032± 0.003	0.068± 0.007	0.378± 0.015	0.440± 0.020
10000 ppm	10	148± 8**	0.117± 0.010	0.030± 0.003	0.060± 0.012	0.370± 0.021	0.435± 0.017
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett							

(HCL042)

BAIS 4

STUDY NO. : 0719
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)
SURVIVAL ANIMALS (14W)

PAGE : 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.667± 0.032	0.234± 0.013	2.343± 0.067	1.028± 0.062
256 ppm	10	0.695± 0.031	0.226± 0.011	2.347± 0.066	1.074± 0.046
640 ppm	10	0.679± 0.021	0.225± 0.008	2.347± 0.046	1.064± 0.034
1600 ppm	10	0.684± 0.034	0.230± 0.011	2.362± 0.072	1.095± 0.066*
4000 ppm	10	0.717± 0.019**	0.228± 0.010	2.465± 0.081**	1.142± 0.035**
10000 ppm	10	0.726± 0.028**	0.233± 0.017	2.626± 0.101**	1.173± 0.055**
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett					

(HCL042)

BAIS 4

TABLE L 1

HISTOPATHOLOGICAL FINDINGS:

NON-NEOPLASTIC LESIONS:MALE: ALL ANIMALS

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 1

Organ_____	Findings_____	Group Name No. of Animals on Study Grade	Control 10				256 ppm 10				640 ppm 10				1600 ppm 10			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Hematopoietic system)																		
thymus			<10>				<10>				<10>				<10>			
	atrophy		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)
	congestion		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)
(Circulatory system)																		
heart			<10>				<10>				<10>				<10>			
	inflammatory cell nest		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	1 (10)	0 (0)	0 (0)
(Digestive system)																		
stomach			<10>				<10>				<10>				<10>			
	hyperplasia:forestomach		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	8 (80)	0 (0)	0 (0)	0 (0) **
			<10>				<10>				<10>				<10>			
liver			1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 2

Organ	Findings	Group Name No. of Animals on Study Grade	4000 ppm				10000 ppm			
			10				10			
			1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Hematopoietic system}										
thymus	atrophy		<10>				<10>			
			0	0	0	0	10	0	0	0 **
			(0)	(0)	(0)	(0)	(100)	(0)	(0)	(0)
	congestion		<10>				<10>			
			0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Circulatory system}										
heart	inflammatory cell nest		<10>				<10>			
			0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Digestive system}										
stomach	hyperplasia:forestomach		<10>				<10>			
			9	0	0	0 **	3	7	0	0 **
			(90)	(0)	(0)	(0)	(30)	(70)	(0)	(0)
liver	herniation		<10>				<10>			
			0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

(HPT150)

BAIS4

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 3

Organ	Findings	Group Name	Control				256 ppm				640 ppm				1600 ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																		
kidney	eosinophilic body		<10>				<10>				<10>				<10>			
			10	0	0	0	10	0	0	0	10	0	0	0	9	1	0	0
			(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(90)	(10)	(0)	(0)
	mineralization:papilla		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	regeneration:proximal tubule		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Endocrine system}																		
pituitary	Rathke pouch		<10>				<10>				<10>				<10>			
			0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
thyroid	ultimobranchial body remanet		<10>				<10>				<10>				<10>			
			0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Reproductive system}																		
testis	atrophy		<10>				<10>				<10>				<10>			
			0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 4

		Group Name	4000 ppm				10000 ppm			
		No. of Animals on Study	10				10			
Organ	Findings	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}										
kidney			<10>				<10>			
	eosinophilic body		10	0	0	0	10	0	0	0
			(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)
	mineralization:papilla		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	regeneration:proximal tubule		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Endocrine system}										
pituitary			<10>				<10>			
	Rathke pouch		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
thyroid			<10>				<10>			
	ultimobranchial body remanet		1	0	0	0	2	0	0	0
			(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
{Reproductive system}										
testis			<10>				<10>			
	atrophy		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 5

Organ_____	Findings_____	Group Name	Control				256 ppm				640 ppm				1600 ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

{Special sense organs/appendage}

Harder gl	lymphocytic infiltration	<10>				<10>				<10>				<10>			
		1	0	0	0	1	0	0	0	2	0	0	0	1	0	0	0
		(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

(HPT150)

BAIS4

STUDY NO. : 0719
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 6

Organ	Findings	Group Name				4000 ppm				10000 ppm							
		No. of Animals on Study				10				10							
		Grade				1				2							
		3				4				1				2			
		1				2				3				4			
		(%)				(%)				(%)				(%)			

{Special sense organs/appendage}

Harder gl	lymphocytic infiltration	<10>				<10>			
		1	0	0	0	1	0	0	0
		(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

(HPT150)

BAIS4

TABLE L 2

HISTOPATHOLOGICAL FINDINGS: NON-NEOPLASTIC
LESIONS: FEMALE: ALL ANIMALS

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 7

		Group Name	Control				256 ppm				640 ppm				1600 ppm			
		No. of Animals on Study	10				10				10				10			
Organ	Findings	Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
nasal cavit			<10>				<10>				<10>				<10>			
	inflammatory infiltration		3	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(30)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
[Hematopoietic system]																		
bone marrow			<10>				<10>				<10>				<10>			
	granulation		2	3	0	0	3	0	0	0	2	1	0	0	1	0	0	0
			(20)	(30)	(0)	(0)	(30)	(0)	(0)	(0)	(20)	(10)	(0)	(0)	(10)	(0)	(0)	(0)
thymus			<10>				<10>				<10>				<10>			
	atrophy		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)
[Digestive system]																		
stomach			<10>				<10>				<10>				<10>			
	hyperplasia:forestomach		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)	(0)	(0)	(40)	(0)	(0)	(0)
liver			<10>				<10>				<10>				<10>			
	herniation		3	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0
			(30)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 8

Organ	Findings	Group Name No. of Animals on Study Grade	4000 ppm 10				10000 ppm 10			
			1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}										
nasal cavit	inflammatory infiltration		<10>				<10>			
			0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Hematopoietic system}										
bone marrow	granulation		<10>				<10>			
			0	0	0	0 *	0	1	0	0
			(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)
thymus	atrophy		<10>				<10>			
			0	0	0	0	3	0	0	0
			(0)	(0)	(0)	(0)	(30)	(0)	(0)	(0)
{Digestive system}										
stomach	hyperplasia:forestomach		<10>				<10>			
			7	1	0	0 **	5	5	0	0 **
			(70)	(10)	(0)	(0)	(50)	(50)	(0)	(0)
liver	herniation		<10>				<10>			
			0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 9

		Group Name	Control				256 ppm				640 ppm				1600 ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Organ	Findings		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}																		
kidney			<10>				<10>				<10>				<10>			
	mineralization:cortico-medullary junction		8	0	0	0	5	0	0	0	5	0	0	0	7	0	0	0
			(80)	(0)	(0)	(0)	(50)	(0)	(0)	(0)	(50)	(0)	(0)	(0)	(70)	(0)	(0)	(0)
	mineralization:papilla		2	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	mineralization:cortex		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Endocrine system}																		
pituitary			<10>				<10>				<10>				<10>			
	Rathke pouch		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
thyroid			<10>				<10>				<10>				<10>			
	ultimobranchial body remanet		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Special sense organs/appendage}																		
Harder gl			<10>				<10>				<10>				<10>			
	lymphocytic infiltration		6	0	0	0	0	1	0	0	4	0	0	0	1	0	0	0
			(60)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(40)	(0)	(0)	(0)	(10)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference : * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0719
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 10

		Group Name	4000 ppm				10000 ppm			
		No. of Animals on Study	10				10			
Organ	Findings	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Urinary system]										
kidney			<10>				<10>			
	mineralization:cortico-medullary junction		8	0	0	0	8	0	0	0
			(80)	(0)	(0)	(0)	(80)	(0)	(0)	(0)
	mineralization:papilla		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
	mineralization:cortex		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Endocrine system]										
pituitary			<10>				<10>			
	Rathke pouch		1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
thyroid			<10>				<10>			
	ultimobranchial body remanet		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
[Special sense organs/appendage]										
Harder gl			<10>				<10>			
	lymphocytic infiltration		0	0	0	0 *	4	0	0	0
			(0)	(0)	(0)	(0)	(40)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
 < a > a : Number of animals examined at the site
 b : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square