

メチルアミンのラットを用いた
吸入による13週間毒性試験報告書

試験番号：0701

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: FEMALE

TABLE A

**CONCENTRATIONS OF METHYLAMINE
IN THE INHALATION CHAMBER
OF THE 13-WEEK INHALATION STUDY**

CONCENTRATIONS OF METHYLAMINE IN THE INHALATION
CHAMBER OF THE 13-WEEK INHALATION STUDY

Group Name	Concentration(ppm)
	Mean \pm S.D.
Control	0.0 \pm 0.0
10 ppm	10.3 \pm 0.5
20 ppm	19.6 \pm 1.1
40 ppm	39.9 \pm 2.4
80 ppm	78.6 \pm 3.0
160 ppm	159.3 \pm 3.6

TABLE B1

SURVIVAL ANIMAL NUMBERS : MALE

STUDY NO. : 0701

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
10ppm	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
20ppm	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
40ppm	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
80ppm	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
160ppm	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(%)															

TABLE B2

SURVIVAL ANIMAL NUMBERS : FEMALE

STUDY NO. : 0701

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
10ppm	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
20ppm	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
40ppm	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
80ppm	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
160ppm	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 C1

CLINICAL OBSERVATION : MALE

STUDY NO. : 0701
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
	10ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	20ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	40ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	80ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	160ppm	10	10	10	10	10	10	10	10	10	10	10	10	10

(HAN190)

BAIS 4

TABLE C2

CLINICAL OBSERVATION : FEMALE

STUDY NO. : 0701
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
NON REMARKABLE	Control	10	10	10	10	10	10	10	10	10	10	10	10	10
	10ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	20ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	40ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	80ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	160ppm	10	10	10	10	10	10	10	10	10	10	10	10	10

(HAN190)

BAIS 4

TABLE D1

**BODY WEIGHT CHANGES AND SURVIVAL ANIMAL
NUMBERS : MALE**

STUDY NO. : 0701
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

MEAN BODY WEIGHTS AND SURVIVAL

PAGE : 1

Week-Day on Study	Control		10ppm			20ppm			40ppm			80ppm			160ppm		
	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.
0-0	127 (10)	10/10	127 (10)	100	10/10	127 (10)	100	10/10	127 (10)	100	10/10	127 (10)	100	10/10	127 (10)	100	10/10
1-7	159 (10)	10/10	156 (10)	98	10/10	155 (10)	97	10/10	154 (10)	97	10/10	146 (10)	92	10/10	136 (10)	86	10/10
2-7	191 (10)	10/10	188 (10)	98	10/10	185 (10)	97	10/10	183 (10)	96	10/10	172 (10)	90	10/10	159 (10)	83	10/10
3-7	216 (10)	10/10	213 (10)	99	10/10	210 (10)	97	10/10	209 (10)	97	10/10	196 (10)	91	10/10	178 (10)	82	10/10
4-7	238 (10)	10/10	232 (10)	97	10/10	231 (10)	97	10/10	230 (10)	97	10/10	217 (10)	91	10/10	194 (10)	82	10/10
5-7	254 (10)	10/10	247 (10)	97	10/10	247 (10)	97	10/10	246 (10)	97	10/10	232 (10)	91	10/10	207 (10)	81	10/10
6-7	267 (10)	10/10	261 (10)	98	10/10	261 (10)	98	10/10	260 (10)	97	10/10	246 (10)	92	10/10	220 (10)	82	10/10
7-7	280 (10)	10/10	272 (10)	97	10/10	272 (10)	97	10/10	273 (10)	98	10/10	260 (10)	93	10/10	229 (10)	82	10/10
8-7	294 (10)	10/10	285 (10)	97	10/10	285 (10)	97	10/10	284 (10)	97	10/10	273 (10)	93	10/10	238 (10)	81	10/10
9-7	301 (10)	10/10	292 (10)	97	10/10	295 (10)	98	10/10	291 (10)	97	10/10	282 (10)	94	10/10	247 (10)	82	10/10
10-7	309 (10)	10/10	300 (10)	97	10/10	300 (10)	97	10/10	299 (10)	97	10/10	292 (10)	94	10/10	259 (10)	84	10/10
11-7	312 (10)	10/10	305 (10)	98	10/10	303 (10)	97	10/10	301 (10)	96	10/10	294 (10)	94	10/10	258 (10)	83	10/10
12-7	322 (10)	10/10	312 (10)	97	10/10	309 (10)	96	10/10	309 (10)	96	10/10	306 (10)	95	10/10	270 (10)	84	10/10
13-7	325 (10)	10/10	316 (10)	97	10/10	314 (10)	97	10/10	314 (10)	97	10/10	309 (10)	95	10/10	273 (10)	84	10/10

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

Av. Wt. : g

TABLE D2

**BODY WEIGHT CHANGES AND SURVIVAL ANIMAL
NUMBERS : FEMALE**

STUDY NO. : 0701
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

MEAN BODY WEIGHTS AND SURVIVAL

PAGE : 2

Week-Day on Study	Control		10ppm			20ppm			40ppm			80ppm			160ppm		
	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.
0-0	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
1-7	113 (10)	10/10	110 (10)	97	10/10	110 (10)	97	10/10	110 (10)	97	10/10	105 (10)	93	10/10	100 (10)	88	10/10
2-7	127 (10)	10/10	123 (10)	97	10/10	124 (10)	98	10/10	124 (10)	98	10/10	119 (10)	94	10/10	113 (10)	89	10/10
3-7	139 (10)	10/10	132 (10)	95	10/10	134 (10)	96	10/10	134 (10)	96	10/10	131 (10)	94	10/10	123 (10)	88	10/10
4-7	148 (10)	10/10	141 (10)	95	10/10	144 (10)	97	10/10	142 (10)	96	10/10	138 (10)	93	10/10	130 (10)	88	10/10
5-7	154 (10)	10/10	150 (10)	97	10/10	149 (10)	97	10/10	149 (10)	97	10/10	145 (10)	94	10/10	137 (10)	89	10/10
6-7	161 (10)	10/10	154 (10)	96	10/10	156 (10)	97	10/10	156 (10)	97	10/10	151 (10)	94	10/10	143 (10)	89	10/10
7-7	166 (10)	10/10	158 (10)	95	10/10	160 (10)	96	10/10	160 (10)	96	10/10	157 (10)	95	10/10	148 (10)	89	10/10
8-7	172 (10)	10/10	163 (10)	95	10/10	165 (10)	96	10/10	166 (10)	97	10/10	163 (10)	95	10/10	153 (10)	89	10/10
9-7	174 (10)	10/10	165 (10)	95	10/10	168 (10)	97	10/10	169 (10)	97	10/10	165 (10)	95	10/10	158 (10)	91	10/10
10-7	179 (10)	10/10	170 (10)	95	10/10	172 (10)	96	10/10	174 (10)	97	10/10	170 (10)	95	10/10	162 (10)	91	10/10
11-7	180 (10)	10/10	171 (10)	95	10/10	173 (10)	96	10/10	174 (10)	97	10/10	171 (10)	95	10/10	161 (10)	89	10/10
12-7	186 (10)	10/10	176 (10)	95	10/10	176 (10)	95	10/10	178 (10)	96	10/10	177 (10)	95	10/10	167 (10)	90	10/10
13-7	187 (10)	10/10	176 (10)	94	10/10	177 (10)	95	10/10	179 (10)	96	10/10	178 (10)	95	10/10	168 (10)	90	10/10

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

TABLE D3

BODY WEIGHT CHANGES : MALE

STUDY NO. : 0701
 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-day									
	0-0		1-7		2-7		3-7		4-7		5-7	
Control	127±	5	159±	8	191±	8	216±	7	238±	9	254±	9
10ppm	127±	5	156±	8	188±	9	213±	12	232±	14	247±	15
20ppm	127±	5	155±	6	185±	8	210±	10	231±	12	247±	12
40ppm	127±	5	154±	9	183±	9	209±	10	230±	10	246±	11
80ppm	127±	5	146±	8**	172±	8**	196±	9**	217±	9**	232±	12**
160ppm	127±	6	136±	6**	159±	6**	178±	8**	194±	8**	207±	9**

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

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(HAN260)

BAIS 4

STUDY NO. : 0701
 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-day									
	7-7		8-7		9-7		10-7		11-7		12-7	
Control	280±	13	294±	12	301±	14	309±	13	312±	14	322±	14
10ppm	272±	19	285±	19	292±	20	300±	19	305±	20	312±	20
20ppm	272±	13	285±	14	295±	16	300±	16	303±	15	309±	16
40ppm	273±	12	284±	12	291±	10	299±	11	301±	12	309±	13
80ppm	260±	13**	273±	14**	282±	15*	292±	15*	294±	15*	306±	16
160ppm	229±	9**	238±	10**	247±	10**	259±	10**	258±	12**	270±	12**

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

Test of Dunnett

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TABLE D4

BODY WEIGHT CHANGES : FEMALE

STUDY NO. : 0701
 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-day											
	0-0		1-7		2-7		3-7		4-7		5-7		6-7	
Control	97±	3	113±	3	127±	3	139±	4	148±	4	154±	4	161±	4
10ppm	97±	3	110±	4	123±	4	132±	6*	141±	4*	150±	6	154±	6
20ppm	97±	3	110±	4	124±	4	134±	5	144±	5	149±	5	156±	6
40ppm	97±	3	110±	3	124±	4	134±	5	142±	5	149±	5	156±	7
80ppm	97±	3	105±	5**	119±	6**	131±	7**	138±	6**	145±	7**	151±	9*
160ppm	97±	3	100±	6**	113±	5**	123±	6**	130±	7**	137±	7**	143±	8**

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

Test of Dunnett

STUDY NO. : 0701
 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-day													
	7-7		8-7		9-7		10-7		11-7		12-7		13-7			
Control	166±	6	172±	6	174±	7	179±	7	180±	8	186±	8	187±	7		
10ppm	158±	7	163±	7*	165±	7	170±	9	171±	9	176±	10	176±	10*		
20ppm	160±	8	165±	7	168±	8	172±	7	173±	7	176±	7	177±	7*		
40ppm	160±	7	166±	7	169±	8	174±	8	174±	6	178±	7	179±	7		
80ppm	157±	9*	163±	9*	165±	9	170±	10	171±	9	177±	11	178±	9		
160ppm	148±	8**	153±	8**	158±	9**	162±	9**	161±	9**	167±	8**	168±	8**		

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

Test of Dunnett

TABLE E1

**FOOD CONSUMPTION CHANGES AND SURVIVAL ANIMAL
NUMBERS : MALE**

STUDY NO. : 0701
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : MALE

MEAN FOOD CONSUMPTION(FC) AND SURVIVAL

PAGE : 1

Week-Day on Study	Control		10ppm			20ppm			40ppm			80ppm			160ppm		
	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.
1-7	14.5 (10)	10/10	14.4 (10)	99	10/10	14.1 (10)	97	10/10	13.4 (10)	92	10/10	12.1 (10)	83	10/10	10.5 (10)	72	10/10
2-7	16.1 (10)	10/10	16.0 (10)	99	10/10	15.5 (10)	96	10/10	15.0 (10)	93	10/10	13.9 (10)	86	10/10	12.6 (10)	78	10/10
3-7	17.1 (10)	10/10	16.9 (10)	99	10/10	16.6 (10)	97	10/10	16.8 (10)	98	10/10	15.4 (10)	90	10/10	13.9 (10)	81	10/10
4-7	17.0 (10)	10/10	17.1 (10)	101	10/10	16.6 (10)	98	10/10	17.0 (10)	100	10/10	16.2 (10)	95	10/10	14.4 (10)	85	10/10
5-7	17.0 (10)	10/10	16.6 (10)	98	10/10	16.6 (10)	98	10/10	16.1 (10)	95	10/10	15.7 (10)	92	10/10	14.2 (10)	84	10/10
6-7	16.8 (10)	10/10	16.7 (10)	99	10/10	16.6 (10)	99	10/10	16.5 (10)	98	10/10	15.9 (10)	95	10/10	14.8 (10)	88	10/10
7-7	17.0 (10)	10/10	16.7 (10)	98	10/10	16.4 (10)	96	10/10	16.3 (10)	96	10/10	15.7 (10)	92	10/10	14.5 (10)	85	10/10
8-7	17.4 (10)	10/10	16.6 (10)	95	10/10	16.9 (10)	97	10/10	16.3 (10)	94	10/10	16.1 (10)	93	10/10	14.9 (10)	86	10/10
9-7	17.1 (10)	10/10	16.4 (10)	96	10/10	16.7 (10)	98	10/10	16.0 (10)	94	10/10	16.0 (10)	94	10/10	14.9 (10)	87	10/10
10-7	16.7 (10)	10/10	16.3 (10)	98	10/10	16.5 (10)	99	10/10	16.2 (10)	97	10/10	16.3 (10)	98	10/10	15.5 (10)	93	10/10
11-7	17.0 (10)	10/10	16.5 (10)	97	10/10	16.3 (10)	96	10/10	16.0 (10)	94	10/10	16.1 (10)	95	10/10	14.9 (10)	88	10/10
12-7	16.6 (10)	10/10	15.9 (10)	96	10/10	15.9 (10)	96	10/10	16.1 (10)	97	10/10	16.5 (10)	99	10/10	16.3 (10)	98	10/10
13-7	15.9 (10)	10/10	15.4 (10)	97	10/10	15.2 (10)	96	10/10	15.2 (10)	96	10/10	15.3 (10)	96	10/10	14.1 (10)	89	10/10
< >:No. of effective animals, () :No. of measured animals Av. FC. : g																	

(BI0040)

BAIS 4

TABLE E2

**FOOD CONSUMPTION CHANGES AND SURVIVAL ANIMAL
NUMBERS : FEMALE**

STUDY NO. : 0701
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

MEAN FOOD CONSUMPTION(FC) AND SURVIVAL

PAGE : 2

Week-Day on Study	Control		10ppm			20ppm			40ppm			80ppm			160ppm		
	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.
1-7	10.7 (10)	10/10	10.3 (10)	96	10/10	10.3 (10)	96	10/10	10.1 (10)	94	10/10	9.2 (10)	86	10/10	8.6 (10)	80	10/10
2-7	11.1 (9)	10/10	10.8 (10)	97	10/10	11.1 (10)	100	10/10	10.9 (10)	98	10/10	9.7 (10)	87	10/10	9.8 (10)	88	10/10
3-7	11.6 (10)	10/10	10.9 (10)	94	10/10	11.3 (10)	97	10/10	11.5 (10)	99	10/10	10.6 (10)	91	10/10	10.4 (10)	90	10/10
4-7	11.8 (10)	10/10	11.0 (10)	93	10/10	11.2 (10)	95	10/10	11.7 (10)	99	10/10	10.6 (10)	90	10/10	10.3 (10)	87	10/10
5-7	11.3 (10)	10/10	10.7 (10)	95	10/10	10.9 (10)	96	10/10	11.1 (10)	98	10/10	10.7 (10)	95	10/10	10.2 (10)	90	10/10
6-7	11.8 (10)	10/10	10.8 (10)	92	10/10	10.8 (10)	92	10/10	11.5 (10)	97	10/10	10.8 (10)	92	10/10	10.8 (10)	92	10/10
7-7	11.6 (10)	10/10	10.5 (10)	91	10/10	10.8 (10)	93	10/10	11.1 (10)	96	10/10	10.9 (10)	94	10/10	10.4 (10)	90	10/10
8-7	11.0 (10)	10/10	10.3 (10)	94	10/10	10.6 (10)	96	10/10	11.2 (10)	102	10/10	11.1 (10)	101	10/10	10.6 (10)	96	10/10
9-7	11.2 (10)	10/10	10.3 (10)	92	10/10	10.8 (10)	96	10/10	11.2 (10)	100	10/10	10.7 (10)	96	10/10	10.6 (10)	95	10/10
10-7	11.3 (10)	10/10	10.8 (10)	96	10/10	10.6 (10)	94	10/10	11.2 (10)	99	10/10	10.9 (10)	96	10/10	11.0 (10)	97	10/10
11-7	11.7 (10)	10/10	10.8 (10)	92	10/10	10.9 (10)	93	10/10	11.1 (10)	95	10/10	11.1 (10)	95	10/10	10.8 (10)	92	10/10
12-7	11.0 (10)	10/10	10.8 (10)	98	10/10	10.8 (10)	98	10/10	11.0 (10)	100	10/10	11.6 (10)	105	10/10	11.5 (10)	105	10/10
13-7	11.0 (10)	10/10	9.9 (10)	90	10/10	10.1 (10)	92	10/10	10.7 (10)	97	10/10	10.5 (10)	95	10/10	10.3 (10)	94	10/10
< >:No. of effective animals, ():No. of measured animals Av. FC. : g																	

(BI0040)

BAIS 4

TABLE E3

FOOD CONSUMPTION CHANGES : MALE

STUDY NO. : 0701
 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-day(effective)						
	1-7(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	14.5± 1.0	16.1± 1.0	17.1± 0.7	17.0± 0.7	17.0± 0.8	16.8± 0.9	17.0± 1.1
10ppm	14.4± 0.6	16.0± 0.9	16.9± 0.8	17.1± 0.9	16.6± 0.7	16.7± 1.0	16.7± 1.1
20ppm	14.1± 0.8	15.5± 0.8	16.6± 1.1	16.6± 0.9	16.6± 0.8	16.6± 0.8	16.4± 1.0
40ppm	13.4± 1.1*	15.0± 1.0*	16.8± 1.0	17.0± 1.1	16.1± 0.8	16.5± 0.8	16.3± 0.6
80ppm	12.1± 0.7**	13.9± 0.8**	15.4± 0.8**	16.2± 0.8	15.7± 1.0**	15.9± 0.8*	15.7± 0.9*
160ppm	10.5± 0.6**	12.6± 0.3**	13.9± 0.6**	14.4± 0.5**	14.2± 0.7**	14.8± 0.6**	14.5± 0.5**

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

Test of Dunnett

STUDY NO. : 0701
 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 8-7(7)	week-day(effective) 9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)
Control	17.4± 1.0	17.1± 1.2	16.7± 1.2	17.0± 1.1	16.6± 0.9	15.9± 0.9
10ppm	16.6± 0.9	16.4± 1.0	16.3± 1.1	16.5± 1.0	15.9± 1.0	15.4± 1.0
20ppm	16.9± 0.8	16.7± 0.9	16.5± 0.8	16.3± 0.9	15.9± 1.0	15.2± 0.8
40ppm	16.3± 0.7**	16.0± 0.4*	16.2± 0.6	16.0± 0.6*	16.1± 0.7	15.2± 0.6
80ppm	16.1± 0.6**	16.0± 0.8*	16.3± 0.8	16.1± 0.7	16.5± 0.7	15.3± 1.2
160ppm	14.9± 0.3**	14.9± 0.6**	15.5± 0.4**	14.9± 0.7**	16.3± 0.9	14.1± 0.8**

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

Test of Dunnett

TABLE E4

FOOD CONSUMPTION CHANGES : FEMALE

STUDY NO. : 0701
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 1-7(7)	week-day(effective) 2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	10.7± 0.5	11.1± 0.3	11.6± 0.4	11.8± 0.6	11.3± 0.4	11.8± 0.7	11.6± 0.9
10ppm	10.3± 0.6	10.8± 0.5	10.9± 0.8	11.0± 0.5*	10.7± 0.7	10.8± 0.8**	10.5± 0.7**
20ppm	10.3± 0.4	11.1± 0.6	11.3± 0.7	11.2± 0.7	10.9± 0.6	10.8± 0.7*	10.8± 0.6
40ppm	10.1± 0.7	10.9± 0.7	11.5± 0.6	11.7± 0.8	11.1± 0.9	11.5± 0.6	11.1± 0.8
80ppm	9.2± 0.6**	9.7± 0.8**	10.6± 0.6**	10.6± 0.6**	10.7± 0.7	10.8± 0.6**	10.9± 0.6
160ppm	8.6± 0.9**	9.8± 0.5**	10.4± 0.6**	10.3± 0.5**	10.2± 0.6**	10.8± 0.6**	10.4± 0.7**

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

Test of Dunnett

STUDY NO. : 0701
 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 8-7(7)	week-day(effective) 9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)
Control	11.0± 0.8	11.2± 0.9	11.3± 0.7	11.7± 0.9	11.0± 0.9	11.0± 0.6
10ppm	10.3± 0.7*	10.3± 0.8*	10.8± 1.0	10.8± 0.9*	10.8± 0.8	9.9± 0.9**
20ppm	10.6± 0.8	10.8± 0.5	10.6± 0.5	10.9± 0.5	10.8± 0.4	10.1± 0.5**
40ppm	11.2± 0.6	11.2± 0.6	11.2± 0.5	11.1± 0.3	11.0± 0.3	10.7± 0.5
80ppm	11.1± 0.6	10.7± 0.7	10.9± 0.8	11.1± 0.6	11.6± 0.5	10.5± 0.3
160ppm	10.6± 0.4	10.6± 0.6	11.0± 0.7	10.8± 0.5*	11.5± 0.6	10.3± 0.4

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

Test of Dunnett

TABLE F1

HEMATOLOGY : MALE

STUDY NO. : 0701
 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	9.46±	0.15	15.9±	0.2	46.0±	0.6	48.6±	0.4	16.8±	0.2	34.5±	0.4	773±	58
10ppm	10	9.46±	0.21	15.8±	0.3	46.1±	0.6	48.7±	0.6	16.7±	0.2	34.3±	0.3	770±	46
20ppm	10	9.40±	0.17	15.8±	0.4	45.7±	0.8	48.6±	0.4	16.8±	0.2	34.6±	0.3	769±	45
40ppm	10	9.42±	0.12	15.9±	0.3	45.9±	0.6	48.7±	0.5	16.8±	0.3	34.6±	0.4	761±	42
80ppm	10	9.43±	0.15	15.9±	0.3	46.0±	0.7	48.8±	0.3	16.8±	0.2	34.5±	0.4	770±	40
160ppm	10	9.46±	0.20	16.1±	0.4	46.2±	0.9	48.8±	0.4	17.0±	0.2	34.8±	0.4	766±	53

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

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0701
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
MEASURE. TIME : 1
SEX : MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (14W)

PAGE : 2

Group Name	NO. of Animals	RETICULOCYTE %		PROTHROMBIN TIME s e c		APTT s e c	
Control	10	1.8±	0.2	14.6±	2.2	23.3±	1.5
10ppm	10	1.7±	0.2	12.9±	0.8	22.3±	1.9
20ppm	10	1.7±	0.1	12.6±	0.9	22.0±	1.1
40ppm	10	1.7±	0.2	13.8±	1.7	23.0±	2.0
80ppm	10	1.8±	0.2	13.2±	1.1	23.3±	3.4
160ppm	10	1.7±	0.2	13.9±	1.5	23.5±	1.9

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

Test of Dunnett

STUDY NO. : 0701
 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 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	10	6.75±	1.35	2±	1	22±	4	1±	0	0±	0	3±	0	71±	5	0±	0
10ppm	10	5.93±	1.20	2±	1	22±	4	2±	1	0±	0	3±	1	72±	4	0±	0
20ppm	10	6.46±	1.17	2±	2	23±	3	1±	1	0±	0	3±	1	71±	4	0±	0
40ppm	10	6.67±	1.53	2±	1	23±	5	1±	1	0±	0	3±	1	71±	5	0±	0
80ppm	10	6.68±	1.80	1±	1	22±	4	1±	1	0±	0	3±	1	73±	6	0±	0
160ppm	10	5.95±	1.64	3±	2	23±	7	1±	0	0±	0	3±	1	70±	8	0±	0

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

Test of Dunnett

(HCL070)

BAIS 4

TABLE F2

HEMATOLOGY : FEMALE

STUDY NO. : 0701
 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	8.61±	0.28	15.9±	0.5	44.3±	1.1	51.5±	0.5	18.4±	0.2	35.8±	0.4	822±	80
10ppm	10	8.69±	0.22	16.0±	0.4	44.7±	1.1	51.4±	0.5	18.4±	0.3	35.8±	0.6	822±	32
20ppm	10	8.74±	0.19	16.1±	0.4	44.9±	1.1	51.4±	0.3	18.4±	0.2	35.7±	0.4	820±	80
40ppm	10	8.76±	0.16	16.1±	0.5	45.0±	1.0	51.4±	0.3	18.3±	0.3	35.7±	0.4	793±	53
80ppm	10	8.79±	0.10	16.2±	0.2	45.1±	0.7	51.3±	0.5	18.4±	0.4	35.9±	0.8	806±	66
160ppm	10	8.87±	0.19	16.1±	0.4	45.3±	0.8	51.0±	0.4	18.1±	0.2	35.5±	0.4	776±	62

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

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0701
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
MEASURE. TIME : 1
SEX : FEMALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (14W)

PAGE : 5

Group Name	NO. of Animals	RETICULOCYTE %		PROTHROMBIN TIME s e c		APTT s e c	
Control	10	1.9±	0.3	11.9±	0.4	17.4±	0.6
10ppm	10	1.8±	0.2	11.8±	0.4	18.1±	2.5
20ppm	10	1.7±	0.2	11.6±	0.4	17.3±	0.7
40ppm	10	1.8±	0.2	11.8±	0.3	17.5±	1.4
80ppm	10	1.9±	0.2	11.8±	0.5	17.7±	1.5
160ppm	10	1.8±	0.2	11.9±	0.6	17.1±	1.3

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

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0701
 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 1 O ³ /μℓ		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	10	3.91±	0.89	2±	2	21±	2	1±	1	0±	0	3±	1	73±	3	0±	0
10ppm	10	3.94±	1.46	1±	1	23±	3	2±	1	0±	0	3±	1	71±	4	0±	0
20ppm	10	4.84±	1.63	2±	1	24±	10	1±	1	0±	0	3±	2	70±	10	0±	0
40ppm	10	4.44±	1.03	1±	2	21±	5	1±	1	0±	0	2±	1	74±	6	0±	0
80ppm	10	4.52±	1.34	2±	1	18±	3	2±	1	0±	0	2±	1	76±	4	0±	0
160ppm	10	4.71±	1.39	2±	2	21±	4	2±	1	0±	0	3±	1	72±	5	0±	0

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

Test of Dunnett

(HCL070)

BAIS 4

TABLE G1

BIOCHEMISTRY : MALE

STUDY NO. : 0701

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)

ALL ANIMALS (14W)

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±	0.1	3.5±	0.1	1.1±	0.1	0.11±	0.00	180±	16	58±	5	49±	11
10ppm	10	6.6±	0.2	3.5±	0.1	1.2±	0.1	0.11±	0.01	174±	9	59±	4	48±	9
20ppm	10	6.5±	0.2	3.5±	0.1	1.2±	0.1	0.11±	0.01	169±	9	57±	5	46±	10
40ppm	10	6.5±	0.2	3.5±	0.1	1.1±	0.1	0.11±	0.01	176±	5	59±	2	58±	14
80ppm	10	6.4±	0.1*	3.5±	0.1	1.2±	0.0*	0.10±	0.01	176±	9	58±	4	50±	6
160ppm	10	6.3±	0.2**	3.4±	0.1	1.2±	0.1**	0.11±	0.01	169±	13	52±	3**	31±	9**

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

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0701

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)

ALL ANIMALS (14W)

PAGE : 2

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	111±	9	108±	27	56±	8	216±	50	242±	19	1±	0	112±	8
10ppm	10	110±	5	101±	25	53±	9	213±	53	242±	24	1±	0	116±	15
20ppm	10	108±	7	96±	26	50±	9	214±	71	240±	14	1±	0	120±	16
40ppm	10	113±	5	98±	21	51±	10	223±	53	237±	9	1±	1	120±	17
80ppm	10	110±	6	93±	30	46±	9	205±	66	236±	26	1±	1	123±	18
160ppm	10	102±	7*	78±	9	39±	4**	159±	29	255±	20	1±	0	118±	10

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

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0701

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)

ALL ANIMALS (14W)

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	17.8±	1.8	0.5±	0.0	143±	1	3.5±	0.2	104±	1	10.3±	0.1	5.5±	0.7
10ppm	10	18.0±	1.4	0.5±	0.0	144±	1	3.4±	0.3	105±	1	10.1±	0.2	5.3±	1.0
20ppm	10	18.5±	0.8	0.5±	0.1	143±	1	3.5±	0.3	104±	2	10.1±	0.2	5.5±	0.9
40ppm	10	19.3±	1.2*	0.6±	0.1	143±	2	3.3±	0.2	104±	2	10.1±	0.1	5.5±	1.0
80ppm	10	19.2±	0.6	0.5±	0.0	144±	1	3.5±	0.3	105±	1	10.1±	0.1	5.6±	0.8
160ppm	10	21.0±	0.6**	0.6±	0.1	143±	1	3.5±	0.3	105±	2	9.9±	0.2**	5.8±	1.0

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

Test of Dunnett

(HCL074)

BAIS 4

TABLE G2

BIOCHEMISTRY : FEMALE

STUDY NO. : 0701

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)

ALL ANIMALS (14W)

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	6.4±	0.1	3.5±	0.1	1.2±	0.1	0.12±	0.01	141±	11	71±	5	11±	3
10ppm	10	6.3±	0.1	3.4±	0.1	1.2±	0.0	0.12±	0.01	142±	11	69±	6	10±	2
20ppm	10	6.2±	0.3*	3.4±	0.2	1.2±	0.1	0.11±	0.01	139±	14	68±	9	13±	6
40ppm	10	6.2±	0.2*	3.4±	0.1	1.2±	0.0	0.12±	0.01	140±	12	67±	8	11±	4
80ppm	10	6.1±	0.1**	3.4±	0.1	1.3±	0.0**	0.12±	0.01	140±	8	67±	5	11±	3
160ppm	10	5.9±	0.2**	3.3±	0.1**	1.3±	0.1**	0.12±	0.01	145±	12	60±	7**	10±	2

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

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0701
 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	140±	6	71±	4	35±	4	189±	49	188±	18	1±	1	113±	17
10ppm	10	133±	9	74±	6	34±	3	240±	77	195±	11	1±	1	129±	26
20ppm	10	131±	13	75±	7	37±	9	203±	61	195±	16	2±	1	124±	31
40ppm	10	130±	12	78±	10	38±	8	204±	55	200±	19	2±	1	121±	24
80ppm	10	129±	9	76±	6	39±	6	200±	90	203±	17	2±	1	121±	27
160ppm	10	118±	10**	76±	4	36±	3	201±	65	225±	18**	2±	0	122±	18

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

Test of Dunnett

STUDY NO. : 0701
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 MEASURE. TIME : 1
 SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

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	19.4±	2.0	0.6±	0.1	142±	1	3.2±	0.2	106±	1	9.9±	0.2	4.6±	1.0
10ppm	10	19.5±	1.8	0.5±	0.1	143±	1	3.5±	0.2	106±	1	9.8±	0.2	4.9±	1.0
20ppm	10	19.2±	1.9	0.6±	0.1	142±	1	3.4±	0.2	106±	2	9.8±	0.2	4.6±	1.2
40ppm	10	19.1±	1.6	0.5±	0.0	142±	1	3.5±	0.3*	106±	1	9.8±	0.2	4.8±	1.3
80ppm	10	20.5±	1.7	0.5±	0.0	143±	1	3.5±	0.2	106±	1	9.8±	0.1	4.9±	1.2
160ppm	10	21.1±	1.9	0.5±	0.1	142±	1	3.7±	0.1**	106±	1	9.6±	0.2**	5.4±	1.3

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

Test of Dunnett

(HCL074)

BAIS 4

TABLE H1

URINALYSIS : MALE

STUDY NO. : 0701

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE TIME : 1

SEX : MALE

REPORT TYPE : A1

URINALYSIS

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+	3+	
Control	10	0	0	0	1	1	3	5		1	6	3	0	0	0		10	0	0	0	0	0		7	3	0	0	0	0		10	0	0	0	
10ppm	10	0	0	0	1	4	3	2		4	6	0	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	
20ppm	10	0	0	0	1	4	3	2		5	3	1	1	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	
40ppm	10	0	0	0	1	4	4	1		3	5	2	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	
80ppm	10	0	0	0	1	1	3	5		3	3	3	1	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	
160ppm	10	0	0	0	2	2	3	3		4	3	2	1	0	0		10	0	0	0	0	0		10	0	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. : 0701

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

URINALYSIS

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
10ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
20ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
40ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
80ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
160ppm	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)

BAIS 4

TABLE H2

URINALYSIS : FEMALE

STUDY NO. : 0701

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

URINALYSIS

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+				
Control	10	0	0	0	0	1	5	4		6	1	3	0	0	0			10	0	0	0	0	0			7	3	0	0	0	0			10	0	0	0	
10ppm	10	0	0	0	0	0	5	5		6	3	1	0	0	0			10	0	0	0	0	0			8	2	0	0	0	0			10	0	0	0	
20ppm	10	0	0	0	0	2	5	3		5	4	1	0	0	0			10	0	0	0	0	0			10	0	0	0	0	0			10	0	0	0	
40ppm	10	0	0	0	1	2	6	1		7	2	1	0	0	0			10	0	0	0	0	0			9	1	0	0	0	0			10	0	0	0	
80ppm	10	0	0	0	0	0	6	4		7	2	1	0	0	0			10	0	0	0	0	0			10	0	0	0	0	0			10	0	0	0	
160ppm	10	0	0	0	0	2	5	3		6	2	2	0	0	0			10	0	0	0	0	0			9	1	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. : 0701

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

URINALYSIS

PAGE : 4

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
10ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
20ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
40ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
80ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
160ppm	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)

BAIS 4

TABLE I 1

GROSS FINDINGS : MALE

STUDY NO. : 0701
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control		10ppm		20ppm		40ppm	
			10	(%)	10	(%)	10	(%)	10	(%)
liver	, herniation		1	(10)	0	(0)	1	(10)	2	(20)
testis	white zone		0	(0)	0	(0)	0	(0)	0	(0)

(HPT080)

BAIS 4

STUDY NO. : 0701
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name NO. of Animals	80ppm		160ppm	
			10	(%)	10	(%)
liver	herniation		0	(0)	0	(0)
testis	white zone		1	(10)	0	(0)

(HPT080)

BAIS 4

TABLE I 2

GROSS FINDINGS : FEMALE

STUDY NO. : 0701
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 3

Organ	Findings	Group Name		Control		10ppm		20ppm		40ppm	
		NO. of Animals		10	(%)	10	(%)	10	(%)	10	(%)
liver	herniation			4	(40)	3	(30)	2	(20)	1	(10)

(HPT080)

BAIS 4

STUDY NO. : 0701
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
REPORT TYPE : A1
SEX : FEMALE

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

PAGE : 4

Organ	Findings	Group Name		80ppm		160ppm	
		NO. of Animals		10	(%)	10	(%)
liver	herniation			2	(20)	1	(10)

(HPT080)

BAIS 4

TABLE J1

ORGAN WEIGHT, ABSOLUTE : MALE

STUDY NO. : 0701
 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	303± 14	0.236± 0.035	0.047± 0.004	3.152± 0.130	0.928± 0.042	0.978± 0.051
10ppm	10	295± 20	0.243± 0.032	0.050± 0.004	3.188± 0.117	0.911± 0.045	0.959± 0.057
20ppm	10	292± 15	0.219± 0.026	0.047± 0.002	3.144± 0.070	0.917± 0.028	0.970± 0.055
40ppm	10	292± 11	0.226± 0.022	0.045± 0.003	3.173± 0.132	0.917± 0.046	0.970± 0.029
80ppm	10	285± 15*	0.209± 0.037	0.050± 0.004	3.102± 0.146	0.927± 0.053	0.970± 0.067
160ppm	10	247± 12**	0.166± 0.009**	0.054± 0.003**	3.013± 0.127	0.862± 0.041**	0.929± 0.039

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

Test of Dunnett

(HCL040)

BAIS 4

STUDY NO. : 0701
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	1.836±	0.088	0.564±	0.035	7.371±	0.467	1.920±	0.054
10ppm	10	1.739±	0.108	0.552±	0.032	7.163±	0.595	1.905±	0.042
20ppm	10	1.752±	0.059	0.545±	0.024	6.990±	0.368	1.892±	0.042
40ppm	10	1.748±	0.080	0.557±	0.037	7.075±	0.305	1.921±	0.056
80ppm	10	1.759±	0.094	0.539±	0.029	6.934±	0.419	1.914±	0.065
160ppm	10	1.601±	0.085**	0.472±	0.030**	6.040±	0.378**	1.891±	0.047

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

Test of Dunnett

(HCL040)

BAIS 4

TABLE J2

ORGAN WEIGHT, ABSOLUTE : FEMALE

STUDY NO. : 0701
 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	171± 8	0.190± 0.012	0.054± 0.004	0.098± 0.007	0.630± 0.051	0.722± 0.031
10ppm	10	161± 8*	0.168± 0.020*	0.050± 0.003*	0.091± 0.013	0.568± 0.028**	0.698± 0.030
20ppm	10	162± 6	0.179± 0.020	0.054± 0.003	0.095± 0.008	0.614± 0.022	0.726± 0.019
40ppm	10	164± 7	0.194± 0.036	0.053± 0.003	0.100± 0.008	0.614± 0.032	0.719± 0.035
80ppm	10	162± 9	0.177± 0.021	0.053± 0.005	0.095± 0.008	0.599± 0.045	0.718± 0.042
160ppm	10	152± 8**	0.162± 0.014**	0.055± 0.003	0.093± 0.016	0.586± 0.044*	0.712± 0.032

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

Test of Dunnett

(HCL040)

BAIS 4

STUDY NO. : 0701
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	1.108±	0.056	0.381±	0.017	4.046±	0.202	1.765±	0.045
10ppm	10	1.065±	0.048	0.354±	0.023*	3.754±	0.201*	1.733±	0.050
20ppm	10	1.084±	0.034	0.368±	0.025	3.891±	0.257	1.756±	0.044
40ppm	10	1.107±	0.042	0.373±	0.015	3.900±	0.171	1.754±	0.057
80ppm	10	1.100±	0.050	0.366±	0.025	3.818±	0.258	1.750±	0.066
160ppm	10	1.073±	0.057	0.344±	0.020**	3.669±	0.143**	1.727±	0.039

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

Test of Dunnett

(HCL040)

BAIS 4

TABLE K1

ORGAN WEIGHT, RELATIVE : MALE

STUDY NO. : 0701
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	303± 14	0.078± 0.011	0.016± 0.001	1.042± 0.053	0.307± 0.015	0.323± 0.012
10ppm	10	295± 20	0.082± 0.009	0.017± 0.002	1.085± 0.051	0.310± 0.018	0.326± 0.015
20ppm	10	292± 15	0.075± 0.008	0.016± 0.001	1.077± 0.049	0.314± 0.015	0.332± 0.017
40ppm	10	292± 11	0.078± 0.008	0.016± 0.001	1.087± 0.045	0.314± 0.016	0.332± 0.011
80ppm	10	285± 15*	0.073± 0.013	0.018± 0.002*	1.090± 0.049	0.325± 0.013*	0.340± 0.016
160ppm	10	247± 12**	0.067± 0.004*	0.022± 0.002**	1.221± 0.065**	0.349± 0.012**	0.376± 0.018**

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

Test of Dunnett

(HCL042)

BAIS 4

STUDY NO. : 0701
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	0.606± 0.020	0.186± 0.007	2.432± 0.068	0.634± 0.023
10ppm	10	0.591± 0.019	0.188± 0.007	2.429± 0.053	0.649± 0.038
20ppm	10	0.600± 0.021	0.186± 0.004	2.391± 0.064	0.648± 0.031
40ppm	10	0.598± 0.012	0.191± 0.009	2.421± 0.037	0.658± 0.024
80ppm	10	0.617± 0.018	0.189± 0.008	2.432± 0.052	0.672± 0.026*
160ppm	10	0.648± 0.029**	0.191± 0.007	2.442± 0.060	0.767± 0.040**

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

Test of Dunnett

(HCL042)

BAIS 4

TABLE K2

ORGAN WEIGHT, RELATIVE : FEMALE

STUDY NO. : 0701
 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	171± 8	0.112± 0.004	0.032± 0.002	0.058± 0.004	0.369± 0.025	0.423± 0.016
10ppm	10	161± 8*	0.105± 0.014	0.031± 0.001	0.056± 0.006	0.353± 0.025	0.433± 0.017
20ppm	10	162± 6	0.111± 0.011	0.033± 0.002	0.059± 0.005	0.379± 0.010	0.448± 0.017*
40ppm	10	164± 7	0.118± 0.020	0.032± 0.002	0.061± 0.006	0.375± 0.018	0.438± 0.026
80ppm	10	162± 9	0.109± 0.011	0.033± 0.002	0.058± 0.005	0.369± 0.023	0.442± 0.017
160ppm	10	152± 8**	0.107± 0.011	0.037± 0.003**	0.061± 0.010	0.386± 0.025	0.469± 0.030**

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

Test of Dunnett

(HCL042)

BAIS 4

STUDY NO. : 0701
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	0.649± 0.015	0.223± 0.009	2.370± 0.091	1.035± 0.050
10ppm	10	0.661± 0.026	0.220± 0.011	2.329± 0.072	1.077± 0.059
20ppm	10	0.669± 0.019	0.227± 0.015	2.398± 0.116	1.084± 0.050
40ppm	10	0.675± 0.027*	0.228± 0.008	2.378± 0.084	1.071± 0.063
80ppm	10	0.679± 0.017*	0.226± 0.011	2.351± 0.061	1.080± 0.048
160ppm	10	0.706± 0.021**	0.227± 0.011	2.417± 0.099	1.139± 0.068**

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

Test of Dunnett

(HCL042)

BAIS 4

TABLE L1

**HISTOPATHOLOGICAL FINDINGS :
NON-NEOPLASTIC LESIONS : MALE**

STUDY NO. : 0701
 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				10ppm				20ppm				40ppm			
			10				10				10				10			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit																		
	inflammation:squamous epithelium		<10>				<10>				<10>				<10>			
			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)
	inflammation:respiratory epithelium		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	squamous cell metaplasia:respiratory epithelium		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)
	ulcer:squamous epithelium		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)
	ulcer:respiratory epithelium		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)
	atrophy:olfactory epithelium		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)
{Circulatory system}																		
heart																		
	inflammatory cell nest		<10>				<10>				<10>				<10>			
			1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(10)	(0)	(0)	(0)	(0)	(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

STUDY NO. : 0701
 ANIMAL : RAT F344/DuCr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 2

		Group Name	80ppm				160ppm			
		No. of Animals on Study	10				10			
Organ	Findings	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}										
nasal cavit			<10>				<10>			
	inflammation:squamous epithelium		4	0	0	0	0	2	8	0 **
			(40)	(0)	(0)	(0)	(0)	(20)	(80)	(0)
	inflammation:respiratory epithelium		10	0	0	0 **	0	9	1	0 **
			(100)	(0)	(0)	(0)	(0)	(90)	(10)	(0)
	squamous cell metaplasia:respiratory epithelium		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
	ulcer:squamous epithelium		0	0	2	0	1	0	9	0 **
			(0)	(0)	(20)	(0)	(10)	(0)	(90)	(0)
	ulcer:respiratory epithelium		0	0	0	0	0	0	10	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(100)	(0)
	atrophy:olfactory epithelium		1	0	0	0	8	0	0	0 **
			(10)	(0)	(0)	(0)	(80)	(0)	(0)	(0)
{Circulatory system}										
heart			<10>				<10>			
	inflammatory cell nest		1	0	0	0	0	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. : 0701
 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 No. of Animals on Study				Control				10ppm				20ppm				40ppm			
		Grade				10				10				10				10			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																					
liver	herniation	<10>				1	0	0	0	0	0	0	0	1	0	0	0	2	0	0	0
		(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
	inflammatory cell nest	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Urinary system}																					
kidney	eosinophilic body	<10>				0	10	0	0	2	8	0	0	0	10	0	0	1	8	0	0
		(0)	(100)	(0)	(0)	(0)	(100)	(0)	(0)	(20)	(80)	(0)	(0)	(0)	(100)	(0)	(0)	(10)	(80)	(0)	(0)
	regeneration:proximal tubule	2	0	0	0	1	0	0	0	2	0	0	0	2	0	0	0	1	0	0	0
		(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Endocrine system}																					
pituitary	Rathke pouch	<10>				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)

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. : 0701
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : MALE

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

PAGE : 4

Organ	Findings	Group Name		80ppm				160ppm			
		No. of Animals on Study		10				10			
		Grade		1	2	3	4	1	2	3	4
				(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}											
liver	herniation			<10>				<10>			
				0	0	0	0	0	0	0	0
				(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammatory cell nest			0	0	0	0	1	0	0	0
				(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Urinary system}											
kidney	eosinophilic body			<10>				<10>			
				1	9	0	0	0	10	0	0
				(10)	(90)	(0)	(0)	(0)	(100)	(0)	(0)
	regeneration:proximal tubule			1	0	0	0	1	0	0	0
				(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Endocrine system}											
pituitary	Rathke pouch			<10>				<10>			
				1	0	0	0	0	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 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. : 0701
 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 No. of Animals on Study Grade	Control				10ppm				20ppm				40ppm			
			10				10				10				10			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

{Reproductive system}

testis	atrophy	<10>				<10>				<10>				<10>			
		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)

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

STUDY NO. : 0701
 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		80ppm				160ppm			
		No. of Animals on Study		10				10			
		Grade		1	2	3	4	1	2	3	4
				(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

{Reproductive system}

testis		<10>				<10>			
	atrophy	1	1	0	0	0	0	0	0
		(10)	(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 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 L2

**HISTOPATHOLOGICAL FINDINGS :
NON-NEOPLASTIC LESIONS : FEMALE**

STUDY NO. : 0701
 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				10ppm				20ppm				40ppm			
		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>			
	inflammation:squamous epithelium		3	0	0	0	1	2	0	0	3	1	0	0	5	0	0	0
			(30)	(0)	(0)	(0)	(10)	(20)	(0)	(0)	(30)	(10)	(0)	(0)	(50)	(0)	(0)	(0)
	inflammation:respiratory epithelium		3	0	0	0	4	0	0	0	2	1	0	0	2	2	0	0
			(30)	(0)	(0)	(0)	(40)	(0)	(0)	(0)	(20)	(10)	(0)	(0)	(20)	(20)	(0)	(0)
	ulcer:squamous epithelium		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)
	ulcer:respiratory epithelium		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)
	atrophy:olfactory epithelium		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)
lung			<10>				<10>				<10>				<10>			
	granulation		0	0	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)	(10)	(0)	(0)	(0)	
	inflammatory cell nest		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)
{Hematopoietic system}																		
bone marrow			<10>				<10>				<10>				<10>			
	granulation		3	2	0	0	2	0	0	0	2	2	0	0	3	0	0	0
		(30)	(20)	(0)	(0)	(20)	(0)	(0)	(0)	(20)	(20)	(0)	(0)	(30)	(0)	(0)	(0)	

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
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STUDY NO. : 0701
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	80ppm				160ppm			
		10				10			
		1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}									
nasal cavit		<10>				<10>			
	inflammation:squamous epithelium	2	0	0	0	8	2	0	0 **
		(20)	(0)	(0)	(0)	(80)	(20)	(0)	(0)
	inflammation:respiratory epithelium	3	0	0	0	4	5	0	0 **
		(30)	(0)	(0)	(0)	(40)	(50)	(0)	(0)
	ulcer:squamous epithelium	0	0	0	0	4	0	1	0 *
		(0)	(0)	(0)	(0)	(40)	(0)	(10)	(0)
	ulcer:respiratory epithelium	0	0	0	0	4	0	3	0 **
		(0)	(0)	(0)	(0)	(40)	(0)	(30)	(0)
	atrophy:olfactory epithelium	0	0	0	0	1	0	0	0
		(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
lung		<10>				<10>			
	granulation	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	inflammatory cell nest	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Hematopoietic system}									
bone marrow		<10>				<10>			
	granulation	1	0	0	0	2	0	0	0
		(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe

< a > a : Number of animals examined at the site

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(c) c : b / a * 100

Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Chi Square

STUDY NO. : 0701
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
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HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 9

Organ	Findings	Group Name No. of Animals on Study Grade	Control				10ppm				20ppm				40ppm			
			10				10				10				10			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
liver	herniation		<10>				<10>				<10>				<10>			
			4	0	0	0	3	0	0	0	2	0	0	0	1	0	0	0
			(40)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Urinary system}																		
kidney	mineralization:cortico-medullary junction		<10>				<10>				<10>				<10>			
			2	0	0	0	1	0	0	0	2	0	0	0	1	0	0	0
			(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
	mineralization:papilla		<10>				<10>				<10>				<10>			
			1	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	tubular cell hyperplasia:solid		<10>				<10>				<10>				<10>			
			0	0	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)	(10)	(0)	(0)	(0)
{Endocrine system}																		
pituitary	Rathke pouch		<10>				<10>				<10>				<10>			
			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)

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

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 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 10

Organ	Findings	80ppm				160ppm			
		10				10			
		1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
(Digestive system)									
liver	herniation	<10>				<10>			
		2	0	0	0	1	0	0	0
		(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
(Urinary system)									
kidney	mineralization:cortico-medullary junction	<10>				<10>			
		3	0	0	0	2	0	0	0
		(30)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
	mineralization:papilla	1	0	0	0	0	0	0	0
		(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	tubular cell hyperplasia:solid	0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
(Endocrine system)									
pituitary	Rathke pouch	<10>				<10>			
		1	0	0	0	0	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. : 0701
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
 SEX : FEMALE

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

PAGE : 11

Organ	Findings	Group Name No. of Animals on Study Grade	Control				10ppm				20ppm				40ppm			
			10				10				10				10			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
thyroid	ultimibranhial body remanet		<10>				<10>				<10>				<10>			
			1	0	0	0	1	0	0	0	1	0	0	0	2	0	0	0
			(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
{Special sense organs/appendage}																		
Harder gl	lymphocytic infiltration		<10>				<10>				<10>				<10>			
			2	3	0	0	1	1	0	0	2	2	0	0	2	0	0	0
			(20)	(30)	(0)	(0)	(10)	(10)	(0)	(0)	(20)	(20)	(0)	(0)	(20)	(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

STUDY NO. : 0701
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]
 REPORT TYPE : A1
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HISTOPATHOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 12

Organ	Findings	Group Name No. of Animals on Study Grade	80ppm				160ppm			
			10				10			
			1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

{Endocrine system}

thyroid	ultimibranhial body remanet	<10>				<10>			
		0	0	0	0	0	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

{Special sense organs/appendage}

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